**PB 93 of 2020**

# National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 8)

*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 28 September 2020

**BEN SLADIC**
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health

## 1 Name of Instrument

(1) This Instrument is the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 8)*.

(2) This Instrument may also be cited as PB 93 of 2020.

## 2 Commencement

This Instrument commences on 1 October 2020.

## 3 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] Part 1, Division 1, Section 4A(2)**

*substitute:*

(2) A medical practitioner is an ***authorised prescriber*** for each of the following HSD pharmaceutical benefits for the purpose of the treatment of hepatitis C:

(a) grazoprevir with elbasvir;

(b) ledipasvir with sofosbuvir;

(c) ribavirin; and

(d) sofosbuvir.

**[2] Schedule 1, entry for Apomorphine**

*substitute:*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Apomorphine | Injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL | Injection | Movapo | TD | C4833 C9561 | 360 | 5 | PB |
| | Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL | Injection | Movapo | TD | C4833 C9561 | 180 | 5 | PB |
| | Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL | Injection | Apomine Solution for Infusion | PF | C10830 C10863 | 90 | 5 | C |
| | Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe | Injection | Movapo PFS | TD | C4833 C9561 | 180 | 5 | PB |
| | Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen | Injection | Apomine Intermittent | PF | C10830 C10863 | 100 | 5 | C |
| | | | Movapo Pen | TD | C10830 C10863 | 100 | 5 | C |

**[3] Schedule 1, entry for Bosentan in each of the forms: Tablet 62.5 mg (as monohydrate); and Tablet 125 mg (as monohydrate)**

*insert in numerical order in the column headed "Circumstances" (all instances):* **C10722 C10724 C10725 C10728 C10795**

**[4] Schedule 1, omit entry for Daclatasvir**

**[5] Schedule 1, entry for Macitentan**

*substitute:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Macitentan | Tablet 10 mg | Oral | Opsumit | JC | C10228 C10236 C10285 C10728 C10845 C10846 C10850 C10869 | P10228 P10236 P10285 | 30 | 0 | D |
| | | | | | C10228 C10236 C10285 C10728 C10845 C10846 C10850 C10869 | P10728 P10845 P10846 P10850 P10869 | 30 | 5 | D |

**[6] Schedule 1, entry for Omalizumab in the form Injection 150 mg in 1 mL single dose pre-filled syringe**

*omit from the text in the column headed "Circumstances":* **C7054**

**[7] Schedule 1, entry for Sildenafil**

*insert in numerical order in the column headed "Circumstances" (all instances):* **C10726 C10732 C10797 C10848 C10868**

**[8] Schedule 1, entry for Tadalafil**

**(a)** *insert in numerical order in the column headed "Circumstances" for the brand "Adcirca":* **C10726 C10731 C10732 C10733 C10799**

**(b)** *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

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| | | | Tadalca | CR | C10228 C10234 C10304 C10726 C10731 C10732 C10733 C10799 | | See Note 1 | See Note 2 | D |

**[9] Schedule 1, entry for Tenofovir with emtricitabine and efavirenz**

*omit:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg | Oral | Atripla | GI | C4470 C4522 | | 60 | 5 | D |

**[10] Schedule 3, entry for Apomorphine**

**(a)** *omit:*

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| | C6813 | | Parkinson disease<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6813 |

**(b)** *insert in numerical order after existing text:*

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| | C10830 | | Parkinson disease<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND<br>The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 10830 |
| | C10863 | | Parkinson disease<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND<br>The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 10863 |

## [11] Schedule 3, entry for Bosentan

*insert in numerical order after existing text:*

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| | C10722 | | Pulmonary arterial hypertension (PAH)<br>Initial 1 (dual therapy - previously untreated patients)<br>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments; | Compliance with Written Authority Required procedures |

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| | | | (2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT;<br>(2) ECHO composite assessment only.<br>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.<br>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.<br>The test results provided must not be more than 2 months old at the time of application.<br>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.<br>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.<br>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. | |
| | C10724 | | Pulmonary arterial hypertension (PAH)<br>Initial 2 (dual therapy - previously treated patients)<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>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<br>The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>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. | Compliance with Authority Required procedures |

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| | | | 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.<br>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.<br>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. | |
| | C10725 | | Pulmonary arterial hypertension (PAH)<br>Grandfathered patients (dual therapy)<br>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<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments;<br>(2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT; | Compliance with Written Authority Required procedures |

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| | | | (2) ECHO composite assessment only.<br>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.<br>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.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10728 | | Pulmonary arterial hypertension (PAH)<br>Continuing treatment (dual therapy)<br>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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| | C10795 | | Pulmonary arterial hypertension (PAH)<br>Initial 3 (dual therapy - change)<br>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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.<br>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. | Compliance with Authority Required procedures |

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

**[12] Schedule 3, omit entry for Daclatasvir**

**[13] Schedule 3, entry for Macitentan**

**(a)** *insert in the column headed "Purposes Code" for the Circumstances Code "C10228":* **P10228**

**(b)** *insert in the column headed "Purposes Code" for the Circumstances Code "C10236":* **P10236**

**(c)** *insert in the column headed "Purposes Code" for the Circumstances Code "C10285":* **P10285**

**(d)** *insert in numerical order after existing text:*

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| | C10728 | P10728 | Pulmonary arterial hypertension (PAH)<br>Continuing treatment (dual therapy)<br>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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| | C10845 | P10845 | Pulmonary arterial hypertension (PAH)<br>Initial 1 (dual therapy - previously untreated patients)<br>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, | Compliance with Written Authority Required procedures |

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| | | | sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments;<br>(2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT;<br>(2) ECHO composite assessment only.<br>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.<br>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.<br>The test results provided must not be more than 2 months old at the time of application.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10846 | P10846 | Pulmonary arterial hypertension (PAH)<br>Grandfathered patients (dual therapy)<br>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<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, | Compliance with Written Authority Required procedures |

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| | | | sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments;<br>(2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT;<br>(2) ECHO composite assessment only.<br>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.<br>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.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10850 | P10850 | Pulmonary arterial hypertension (PAH)<br>Initial 3 (dual therapy - change)<br>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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. | Compliance with Authority Required procedures |

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| | | | 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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.<br>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.<br>Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10869 | P10869 | Pulmonary arterial hypertension (PAH)<br>Initial 2 (dual therapy - previously treated patients)<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>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<br>The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |

## [14] Schedule 3, entry for Octreotide

*omit entry for Circumstances Code "C9233" and substitute:*

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| | C9233 | | Acromegaly<br>The condition must be active; AND<br>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND<br>The treatment must be after failure of other therapy including dopamine agonists; OR<br>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR<br>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 times daily; AND<br>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.<br>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 9233 |

## [15] Schedule 3, entry for Omalizumab

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| | C7054 | | Severe chronic spontaneous urticaria<br>Grandfathering treatment<br>Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017; AND<br>Patient must have documented history of itch and hives that persisted on a daily basis for at least 6 weeks despite treatment with H1 antihistamines prior to commencing non-PBS subsidised treatment with this drug for this condition; AND<br>Patient must have documented history of failure to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy prior to commencing non-PBS subsidised treatment with this drug for this condition; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Must be treated by a clinical immunologist; OR<br>Must be treated by an allergist; OR<br>Must be treated by a dermatologist; OR<br>Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).<br>A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:<br>1) a H2 receptor antagonist (150 mg twice per day); or<br>2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or<br>3) doxepin (up to 25 mg three times a day)<br>If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment | Compliance with Written Authority Required procedures |

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| | | | withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.<br>A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial Grandfather PBS Authority Application - Supporting Information Form which must include:<br>(i) demonstration of failure to achieve an adequate response to standard therapy; and<br>(ii) drug names and doses of standard therapies that the patient has failed; and<br>(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient. | |

**[16] Schedule 3, entry for Riociguat**

*omit entry for Circumstances Code "C6664" and substitute:*

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| | C6664 | | Chronic thromboembolic pulmonary hypertension (CTEPH)<br>Initial treatment<br>Patient must have WHO Functional Class II, III or IV CTEPH; AND<br>The condition must be inoperable by pulmonary endarterectomy; OR<br>The condition must be recurrent or persistent following pulmonary endarterectomy; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Must be treated in a centre with expertise in the management of CTEPH.<br>Patient must be aged 18 years or older.<br>CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:<br>Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm-5measured at least 90 days after start of full anticoagulation; and<br>A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.<br>CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:<br>RHC demonstrating a PVR of greater than 300 dyn*sec*cm-5measured at least 180 days following pulmonary endarterectomy.<br>Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.<br>Applications for authorisation must be in writing and must include:(1) completed authority prescription forms sufficient for dose titration; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction. | Compliance with Written Authority Required procedures |

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| | | | Where it is not possible to perform all 3 tests above 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) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(3) RHC composite assessment only.<br>In circumstance 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.<br>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.<br>The test results provided must not be more than 2 months old at the time of application.<br>Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.<br>Approvals for subsequent authority prescription will be limited to 1 month of treatment, the quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.<br>The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.<br>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. | |

**[17] Schedule 3, entry for Sildenafil**

*insert in numerical order after existing text:*

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| | C10726 | | Pulmonary arterial hypertension (PAH)<br>Initial 1 (dual therapy - previously untreated patients)<br>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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 | Compliance with Written Authority Required procedures |

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| | | | ventricular function.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments;<br>(2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT;<br>(2) ECHO composite assessment only.<br>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.<br>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.<br>The test results provided must not be more than 2 months old at the time of application.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10732 | | Pulmonary arterial hypertension (PAH)<br>Continuing treatment (dual therapy)<br>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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| | C10797 | | Pulmonary arterial hypertension (PAH)<br>Grandfathered patients (dual therapy)<br>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 | Compliance with Written Authority Required procedures |

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| | | | 2020; AND<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments;<br>(2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT;<br>(2) ECHO composite assessment only.<br>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.<br>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.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10848 | | Pulmonary arterial hypertension (PAH)<br>Initial 3 (dual therapy - change) | Compliance with Authority Required procedures |

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| | | | 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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.<br>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.<br>Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10868 | | Pulmonary arterial hypertension (PAH)<br>Initial 2 (dual therapy - previously treated patients)<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>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<br>The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>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.<br>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, | Compliance with Authority Required procedures |

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| | | | based on the dosage recommendations in the TGA-approved Product Information.<br>A maximum of 5 repeats may be requested. | |

**[18] Schedule 3, entry for Tadalafil**

*insert in numerical order after existing text:*

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| | C10726 | | Pulmonary arterial hypertension (PAH)<br>Initial 1 (dual therapy - previously untreated patients)<br>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments;<br>(2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT;<br>(2) ECHO composite assessment only.<br>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. | Compliance with Written Authority Required procedures |

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| | | | 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.<br>The test results provided must not be more than 2 months old at the time of application.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10731 | | Pulmonary arterial hypertension (PAH)<br>Initial 2 (dual therapy - previously treated patients)<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND<br>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<br>The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| | C10732 | | Pulmonary arterial hypertension (PAH)<br>Continuing treatment (dual therapy)<br>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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung | Compliance with Authority Required procedures |

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| | | | disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10733 | | Pulmonary arterial hypertension (PAH)<br>Grandfathered patients (dual therapy)<br>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<br>Patient must have been assessed by a physician with expertise in the management of PAH; AND<br>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:<br>(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<br>(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.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6 Minute Walk Test (6MWT).<br>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:<br>(1) RHC plus ECHO composite assessments;<br>(2) RHC composite assessment plus 6MWT;<br>(3) RHC composite assessment only.<br>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:<br>(1) ECHO composite assessment plus 6MWT;<br>(2) ECHO composite assessment only.<br>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.<br>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 | Compliance with Written Authority Required procedures |

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| | | | of PAH.<br>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.<br>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.<br>A maximum of 5 repeats may be requested. | |
| | C10799 | | Pulmonary arterial hypertension (PAH)<br>Initial 3 (dual therapy - change)<br>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.<br>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.<br>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).<br>(i) An ERA includes bosentan monohydrate, or macitentan.<br>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.<br>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.<br>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.<br>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.<br>Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.<br>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.<br>A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |