



PB 37 of 2020

National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 4)

National Health Act 1953

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 29 April 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. 4)*.
- (2) This Instrument may also be cited as PB 37 of 2020.

2 Commencement

This Instrument commences on 1 May 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] Schedule 1, entry for Ambrisentan in each of the forms: Tablet 5 mg; and Tablet 10 mg

omit from the column headed "Circumstances": **C6089 C6711 C6722 C6734 C6748 C6765** *substitute:* **C10228 C10236 C10285**

[2] Schedule 1, entry for Benralizumab

insert as first entry:

Injection 30 mg in 1 mL single dose pre-filled pen	Injection	Fasenra Pen	AP	C9887 C10264 C10281 C10314	P9887	1	0	D
				C9887 C10264 C10281 C10314	P10281	1	2	D
				C9887 C10264 C10281 C10314	P10264 P10314	1	4	D

[3] Schedule 1, entry for Bosentan in the form Tablet 62.5 mg (as monohydrate)

omit from the column headed "Circumstances" (all instances): **C4628 C6089 C6710 C6734 C6748 C6764 C6776** *substitute (all instances):* **C10228 C10238 C10286 C10305**

[4] Schedule 1, entry for Bosentan in the form Tablet 125 mg (as monohydrate)

omit from the column headed "Circumstances" (all instances): **C6089 C6710 C6734 C6748 C6764 C6776** *substitute (all instances):* **C10228 C10286 C10305**

[5] Schedule 1, entry for Epoprostenol in the form Powder for I.V. infusion 500 micrograms (as sodium)

omit from the column headed "Circumstances" (all instances): **C6123 C6734 C6748 C6945 C6955** *substitute (all instances):* **C10228 C10240 C10241**

[6] Schedule 1, entry for Epoprostenol in the form Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL

omit from the column headed "Circumstances": **C6123 C6734 C6748 C6945 C6955** *substitute:* **C10228 C10240 C10241**

[7] Schedule 1, entry for Epoprostenol in the form Powder for I.V. infusion 1.5 mg (as sodium)

omit from the column headed "Circumstances" (all instances): **C6123 C6734 C6748 C6945 C6955** *substitute (all instances):* **C10228 C10240 C10241**

[8] Schedule 1, entry for Epoprostenol in the form Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL

omit from the column headed "Circumstances": **C6123 C6734 C6748 C6945 C6955** *substitute:* **C10228 C10240 C10241**

[9] Schedule 1, entry for Iloprost

omit from the column headed "Circumstances": **C6089 C6692 C6734 C6747 C6748 C6775** *substitute:* **C10228 C10229 C10284**

[10] Schedule 1, entry for Lenalidomide in each of the forms: Capsule 5 mg; Capsule 10 mg; Capsule 15 mg; and Capsule 25 mg

(a) *omit from the column headed "Circumstances":* **C7381 C7383 C7807 C7808**

(b) *insert in numerical order in the column headed "Circumstances":* **C10349 C10350 C10373 C10421**

- [11] **Schedule 1, entry for Levodopa with carbidopa in the form Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL [Maximum Quantity: 28; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C10160*
 (b) *omit from the column headed "Circumstances": C10169*
 (c) *insert in numerical order in the column headed "Circumstances": C10363 C10375*
- [12] **Schedule 1, entry for Levodopa with carbidopa in the form Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL [Maximum Quantity: 56; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C10160*
 (b) *omit from the column headed "Circumstances": C10169*
 (c) *insert in numerical order in the column headed "Circumstances": C10363 C10375*
 (d) *omit from the column headed "Purposes": P10160 P10169 substitute: P10363 P10375*
- [13] **Schedule 1, entry for Macitentan**
omit from the column headed "Circumstances": C6089 C6693 C6722 C6734 C6735 C6748 substitute: C10228 C10236 C10285
- [14] **Schedule 1, entry for Pasireotide in each of the forms: Injection (modified release) 20 mg (as embonate), vial and diluent syringe; Injection (modified release) 40 mg (as embonate), vial and diluent syringe; and Injection (modified release) 60 mg (as embonate), vial and diluent syringe**
omit from the column headed "Responsible Person": NV substitute: RJ
- [15] **Schedule 1, entry for Riociguat in each of the forms: Tablet 500 micrograms; Tablet 1 mg; Tablet 1.5 mg; Tablet 2 mg; and Tablet 2.5 mg**
 (a) *omit from the column headed "Circumstances": C6690 C6691 C6708 C6720 C6733 C6760*
 (b) *insert in numerical order in the column headed "Circumstances": C10231 C10243 C10245*
- [16] **Schedule 1, entry for Sildenafil**
omit from the column headed "Circumstances" (all instances): C6089 C6723 C6734 C6736 C6748 C6749 substitute (all instances): C10228 C10234 C10304
- [17] **Schedule 1, entry for Tadalafil**
omit from the column headed "Circumstances": C6089 C6709 C6721 C6734 C6748 C6761 substitute: C10228 C10234 C10304
- [18] **Schedule 1, entry for Tenofovir**
substitute:

Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg	Oral	Tenofovir APOTEX	TX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2	D
			Viread	GI	C6980 C6982 C6983 C6984	P10362	60	2	D

				C6992 C6998 C10362					
		Tenofovir APOTEX	TX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D	
		Viread	GI	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D	
Tablet containing tenofovir disoproxil maleate 300 mg	Oral	Tenofovir Disoproxil Mylan	AF	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2	D	
				C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D	
Tablet containing tenofovir disoproxil phosphate 291 mg	Oral	Tenofovir GH	GQ	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2	D	
				C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D	

[19] Schedule 2, after entry for Responsible Person RI

insert:

RJ	Recordati Rare Diseases Australia Pty. Ltd	26 627 263 094
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[20] Schedule 3, entry for Ambrisentan

substitute:

Ambrisentan	C10228		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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</p>	Compliance with Authority Required procedures
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		<p>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.</p>	
	C10236	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) 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.</p>	Compliance with Authority Required procedures
	C10285	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new 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 have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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:</p>	Compliance with Written Authority Required procedures

		<p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>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:</p> <p>(1) RHC plus ECHO composite assessments;</p> <p>(2) RHC composite assessment plus 6MWT;</p> <p>(3) RHC composite assessment only.</p> <p>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:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>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.</p> <p>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.</p> <p>The test results provided must not be more than 2 months old at the time of application.</p> <p>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.</p> <p>A maximum of 5 repeats may be requested.</p>	
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[21] Schedule 3, entry for Bosentan

substitute:

Bosentan	C10228	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p> <p>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.</p> <p>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.</p> <p>A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
	C10238	<p>Pulmonary arterial hypertension (PAH)</p> <p>Cessation of treatment (all patients)</p> <p>Patient must be receiving PBS-subsidised treatment with this PAH agent; AND</p> <p>The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.</p>	Compliance with Authority Required procedures

		Treatment beyond 1 month will not be approved.	
	C10286	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new 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 have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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) two completed authority prescription forms; 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. 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. No repeats will be authorised for this prescription. Prescribers should request the second authority prescription of therapy with either the 62.5 mg tablet or the 125 mg tablet strengths, with the quantity for one month of treatment, based on the dosage</p>	Compliance with Written Authority Required procedures

			recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.	
	C10305		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. 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. No repeats will be authorised for this prescription. Prescribers should request the second authority prescription of therapy with either the 62.5 mg tablet or the 125 mg tablet strengths, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	Compliance with Authority Required procedures

[22] Schedule 3, entry for Epoprostenol

substitute:

Epoprostenol	C10228		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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.</p>	Compliance with Authority Required procedures
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	C10240	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new 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 have WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Written Authority Required procedures
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	C10241		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) 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.</p>	Compliance with Authority Required procedures
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[23] Schedule 3, entry for Iloprost

substitute:

Iloprost	C10228		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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.</p>	Compliance with Authority Required procedures
	C10229		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p>	Compliance with Authority Required procedures

		<p>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.</p> <p>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>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.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C10284	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new 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 have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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:</p>	Compliance with Written Authority Required procedures

		<p>(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 Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.</p>	
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[24] Schedule 3, entry for Lenalidomide

(a) *omit:*

	C7381	<p>Multiple myeloma Initial treatment The condition must be newly diagnosed; AND The condition must be confirmed by a histological diagnosis; AND Patient must be ineligible for a primary stem cell transplantation; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND The treatment must be in combination with dexamethasone. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and (3) a signed patient acknowledgement. To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.</p>	Compliance with Written Authority Required procedures
	C7383	<p>Multiple myeloma Continuing treatment</p>	Compliance with Authority Required procedures

		<p>Patient must have previously been authorised with a PBS prescription with this drug for the condition; AND Patient must not have demonstrated progressive disease; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND The treatment must be in combination with dexamethasone. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
	C7807	<p>Multiple myeloma Continuing PBS-subsidised treatment Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma; AND The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Authority Required procedures
	C7808	<p>Multiple myeloma Initial PBS-subsidised treatment The condition must be confirmed by a histological diagnosis; AND The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must have undergone or be ineligible for a primary stem cell transplant; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference</p>	Compliance with Written Authority Required procedures

		<p>between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and</p> <p>(3) a signed patient acknowledgment.</p> <p>To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.</p> <p>Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</p>	
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(b) insert in numerical order after existing text:

	C10349	<p>Multiple myeloma</p> <p>Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma; AND</p> <p>The treatment must be as monotherapy; OR</p> <p>The treatment must be in combination with dexamethasone; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.</p> <p>Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management</p>	Compliance with Authority Required procedures
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	C10350	<p>Multiple myeloma</p> <p>Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must be as monotherapy; OR</p> <p>The treatment must be in combination with dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must have undergone or be ineligible for a primary stem cell transplant; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and</p> <p>(3) a signed patient acknowledgment.</p> <p>To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of</p>	Compliance with Written Authority Required procedures

		<p>the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.</p> <p>Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</p>	
	C10373	<p>Multiple myeloma</p> <p>Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation</p> <p>The condition must be newly diagnosed; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must be ineligible for a primary stem cell transplantation; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND</p> <p>The treatment must be in combination with dexamethasone.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and</p> <p>(3) a signed patient acknowledgement.</p> <p>To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.</p> <p>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Written Authority Required procedures
	C10421	<p>Multiple myeloma</p> <p>Continuing treatment until progression in patients treated with dual combination therapy (lenalidomide and dexamethasone)</p> <p>Patient must have previously been authorised with a PBS prescription with this drug for the condition; AND</p> <p>Patient must not have demonstrated progressive disease; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND</p> <p>The treatment must be in combination with dexamethasone.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p>	Compliance with Authority Required procedures

			<p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
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[25] Schedule 3, entry for Levodopa with carbidopa

(a) omit

	C10160	P10160	<p>Advanced Parkinson disease</p> <p>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND</p> <p>The treatment must be commenced in a hospital-based movement disorder clinic; AND</p> <p>Patient must be undergoing continuous treatment with a dose greater than 2000 mg of levodopa per day without an overnight break.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10160
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(b) omit

	C10169	P10169	<p>Advanced Parkinson disease</p> <p>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND</p> <p>The treatment must be commenced in a hospital-based movement disorder clinic; AND</p> <p>Patient must be undergoing continuous treatment with a dose greater than 2000 mg of levodopa per day without an overnight break.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10169
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(c) insert in numerical order after existing text:

	C10363	P10363	<p>Advanced Parkinson disease</p> <p>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND</p> <p>The treatment must be commenced in a hospital-based movement disorder clinic; AND</p> <p>Patient must require continuous administration of levodopa without an overnight break; OR</p> <p>Patient must require a total daily dose of more than 2000 mg of levodopa.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10363
	C10375	P10375	<p>Advanced Parkinson disease</p> <p>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND</p> <p>The treatment must be commenced in a hospital-based movement disorder clinic; AND</p> <p>Patient must require continuous administration of levodopa without an overnight break; OR</p> <p>Patient must require a total daily dose of more than 2000 mg of levodopa.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10375

[26] Schedule 3, entry for Macitentan

substitute:

Macitentan	C10228	<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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.</p>	Compliance with Authority Required procedures
	C10236	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) 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.</p>	Compliance with Authority Required procedures
	C10285	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new 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 have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition.</p>	Compliance with Written Authority Required procedures

		<p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p> <p>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.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p> <p>(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</p> <p>(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.</p> <p>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>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:</p> <p>(1) RHC plus ECHO composite assessments;</p> <p>(2) RHC composite assessment plus 6MWT;</p> <p>(3) RHC composite assessment only.</p> <p>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:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>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.</p> <p>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.</p> <p>The test results provided must not be more than 2 months old at the time of application.</p> <p>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.</p> <p>A maximum of 5 repeats may be requested.</p>	
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[27] Schedule 3, entry for Riociguat

(a) *omit:*

	C6690	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (new patients)</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must have been assessed by a physician at a designated hospital; AND</p> <p>Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR</p>	Compliance with Written Authority Required procedures
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		<p>Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; AND</p> <p>Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR</p> <p>Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; AND</p> <p>Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial 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); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 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.</p> <p>Test requirements to establish baseline for initiation of treatment are as follows:</p> <p>The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.</p> <p>Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</p> <ol style="list-style-type: none"> (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. <p>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:</p> <ol style="list-style-type: none"> (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. <p>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.</p> <p>The test results provided must not be more than 2 months old at the time of application.</p> <p>Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.</p> <p>Response to prior vasodilator treatment is defined as follows:</p> <p>For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a</p>	
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		<p>RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>Approvals for prescriptions for dose titration will 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.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>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.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p> <p>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.</p>	
	C6691	<p>Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND Patient must have been assessed by a physician at a designated hospital; AND The treatment must be the sole PBS-subsidised PAH agent 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 Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. 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 term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p>	Compliance with Authority Required procedures
	C6708	<p>Pulmonary arterial hypertension (PAH) First Continuing treatment Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response</p>	Compliance with Written Authority Required procedures

		<p>to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. 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). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made two weeks prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung</p>	
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			disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6720		<p>Pulmonary arterial hypertension (PAH) Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.</p>	Compliance with Authority Required procedures
	C6733		<p>Pulmonary arterial hypertension (PAH) Initial 2 (new 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 at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology); AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial 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); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital</p>	Compliance with Written Authority Required procedures

		<p>systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 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.</p> <p>Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.</p> <p>Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.</p> <p>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.</p> <p>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. The test results provided must not be more than 2 months old at the time of application. Approvals for prescriptions for dose titration will 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. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>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. 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.</p>	
	C6760	<p>Pulmonary arterial hypertension (PAH) Initial 3 (change or re-commencement of therapy for all patients) Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or</p>	Compliance with Authority Required procedures

		<p>hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. 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. The test results provided must not be more than 2 months old at the time of application.</p> <p>Response to a PAH agent is defined as follows:</p> <p>For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>Approvals for prescriptions for dose titration will 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.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>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.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p> <p>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.</p> <p>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the</p>	
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			time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.	
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(b) insert in numerical order after existing text:

	C10231		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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.</p>	Compliance with Authority Required procedures
	C10243		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. Approvals for prescriptions for dose titration will 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. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	Compliance with Authority Required procedures
	C10245		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension</p>	Compliance with Written Authority Required procedures

		<p>(PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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. Approvals for prescriptions for dose titration will 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. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	
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[28] Schedule 3, entry for Sildenafil

substitute:

Sildenafil	C10228	<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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.</p>	Compliance with Authority Required procedures
	C10234	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) 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.</p>	Compliance with Authority Required procedures
	C10304	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new 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 have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p>	Compliance with Written Authority Required procedures

		<p>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.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p> <p>(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</p> <p>(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.</p> <p>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>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:</p> <p>(1) RHC plus ECHO composite assessments;</p> <p>(2) RHC composite assessment plus 6MWT;</p> <p>(3) RHC composite assessment only.</p> <p>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:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>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.</p> <p>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.</p> <p>The test results provided must not be more than 2 months old at the time of application.</p> <p>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.</p> <p>A maximum of 5 repeats may be requested.</p>	
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[29] Schedule 3, entry for Tadalafil

substitute:

Tadalafil	C10228	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.</p> <p>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</p>	Compliance with Authority Required procedures
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		<p>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.</p>	
	C10234	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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 these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) 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.</p>	Compliance with Authority Required procedures
	C10304	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new 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 have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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:</p>	Compliance with Written Authority Required procedures

		<p>(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.</p>	
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[30] Schedule 3, entry for Tenofovir

- (a)** insert in the column headed "Purposes Code" for the circumstance code "C6980": **P6980**
- (b)** insert in the column headed "Purposes Code" for the circumstance code "C6982": **P6982**
- (c)** insert in the column headed "Purposes Code" for the circumstance code "C6983": **P6983**
- (d)** insert in the column headed "Purposes Code" for the circumstance code "C6984": **P6984**
- (e)** insert in the column headed "Purposes Code" for the circumstance code "C6992": **P6992**
- (f)** insert in the column headed "Purposes Code" for the circumstance code "C6998": **P6998**
- (g)** insert in numerical order after existing text:

	C10362	P10362	<p>Chronic hepatitis B infection Patient must be in the third trimester of pregnancy; AND Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10362
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