



PB 121 of 2021

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2021

National Health Act 1953

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

Date 29 November 2021

DAVID LAFFAN
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health

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1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2021*.
- (2) This instrument may also be cited as PB 121 of 2021.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. <i>The whole of this instrument</i>	<i>1 December 2021</i>	<i>1 December 2021</i>

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)

- [1] **Schedule 1, entry for Ambrisentan in each of the forms: Tablet 5 mg; and Tablet 10 mg**
 (a) *omit from the column headed “Circumstances” (all instances): C10228 C10236 C10285*
 (b) *omit from the column headed “Circumstances” (all instances): C11321 C11354*
 (c) *insert in numerical order in the column headed “Circumstances” (all instances): C12433 C12446 C12447 C12460*
- [2] **Schedule 1, entry for Azacitidine**
insert in numerical order in the column headed “Circumstances” (all instances): C12439
- [3] **Schedule 1, entry for Bosentan in the form Tablet 62.5 mg (as monohydrate)**
 (a) *omit from the column headed “Circumstances” (all instances): C10228 C10238 C10924 C10945*
 (b) *omit from the column headed “Circumstances” (all instances): C11317 C11321*
 (c) *insert in numerical order in the column headed “Circumstances” (all instances): C12406 C12423 C12425 C12427 C12458*
- [4] **Schedule 1, entry for Bosentan in the form Tablet 125 mg (as monohydrate)**
 (a) *omit from the column headed “Circumstances” (all instances): C10228 C10924 C10945*
 (b) *omit from the column headed “Circumstances” (all instances): C11317 C11321*
 (c) *insert in numerical order in the column headed “Circumstances” (all instances): C12406 C12423 C12427 C12458*
- [5] **Schedule 1, entry for Ciclosporin in each of the forms: Capsule 25 mg; Capsule 50 mg; and Capsule 100 mg**
insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

APO-Ciclosporin	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764	120	5
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- [6] **Schedule 1, entry for Deferasirox in the form Tablet 90 mg [Maximum Quantity: 180; Number of Repeats: 2]**
insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

DEFERASIROX-TEVA	C7374 C7375	P7385 P8326	180	2
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			C7385 C8326	P8328 P8329		
			C8328 C8329	P9222 P9258		
			C9222 C9258	P9302		
			C9302			

[7] Schedule 1, entry for Deferasirox in the form Tablet 90 mg [Maximum Quantity: 180; Number of Repeats: 5]

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			DEFERASIROX-TEVA	C7374 C7375	P7374 P7375	180	5
				C7385 C8326			
				C8328 C8329			
				C9222 C9258			
				C9302			

[8] Schedule 1, entry for Deferasirox in the form Tablet 180 mg [Maximum Quantity: 180; Number of Repeats: 2]

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			DEFERASIROX-TEVA	C7374 C7375	P7385 P8326	180	2
				C7385 C8326	P8328 P8329		
				C8328 C8329	P9222 P9258		
				C9222 C9258	P9302		
				C9302			

[9] Schedule 1, entry for Deferasirox in the form Tablet 180 mg [Maximum Quantity: 180; Number of Repeats: 5]

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			DEFERASIROX-TEVA	C7374 C7375	P7374 P7375	180	5
				C7385 C8326			
				C8328 C8329			
				C9222 C9258			
				C9302			

[10] Schedule 1, entry for Deferasirox in the form Tablet 360 mg [Maximum Quantity: 180; Number of Repeats: 2]

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			DEFERASIROX-TEVA	C7374 C7375	P7385 P8326	180	2
				C7385 C8326	P8328 P8329		
				C8328 C8329	P9222 P9258		
				C9222 C9258	P9302		
				C9302			

[11] Schedule 1, entry for Deferasirox in the form Tablet 360 mg [Maximum Quantity: 180; Number of Repeats: 5]

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

DEFERASIROX-TEVA	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
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[12] Schedule 1, entry for Entecavir in the form Tablet 0.5 mg (as monohydrate)

omit:

Entecavir Amneal	C4993 C5036		60	5
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[13] Schedule 1, entry for Entecavir in the form Tablet 1 mg (as monohydrate)

omit:

Entecavir Amneal	C5037 C5044		60	5
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[14] Schedule 1, entry for Epoprostenol in the form Powder for I.V. infusion 500 micrograms (as sodium)

- (a) *omit from the column headed "Circumstances" (all instances):* **C10241**
- (b) *omit from the column headed "Circumstances" (all instances):* **C11325**
- (c) *insert in numerical order in the column headed "Circumstances" (all instances):* **C12411 C12454**

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

- (a) *omit from the column headed "Circumstances":* **C10241**
- (b) *omit from the column headed "Circumstances":* **C11325**
- (c) *insert in numerical order in the column headed "Circumstances":* **C12411 C12454**

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

- (a) *omit from the column headed "Circumstances" (all instances):* **C10241**
- (b) *omit from the column headed "Circumstances" (all instances):* **C11325**
- (c) *insert in numerical order in the column headed "Circumstances" (all instances):* **C12411 C12454**

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

- (a) *omit from the column headed "Circumstances":* **C10241**

- (b) omit from the column headed "Circumstances": **C11325**
- (c) insert in numerical order in the column headed "Circumstances": **C12411 C12454**

[18] Schedule 1, entry for Etanercept in each of the forms: Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL; Injections 50 mg in 1 mL single use pre-filled syringes, 4; and Injection 50 mg in 1 mL single use auto injector, 4

- (a) omit from the column headed "Circumstances": **C12358**
- (b) insert in numerical order in the column headed "Circumstances": **C12407**

[19] Schedule 1, entry for Macitentan

- (a) omit from the column headed "Circumstances": **C10228 C10236 C10285**
- (b) omit from the column headed "Circumstances": **C11317 C11321**
- (c) insert in numerical order in the column headed "Circumstances": **C12402 C12403 C12420 C12463**

[20] Schedule 1, entry for Mycophenolic Acid in the form Tablet containing mycophenolate mofetil 500 mg

omit:

	Mycophenolate AN	C5554 C5795 C9691 C9693	300	5
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[21] Schedule 1, entry for Nevirapine in the form Tablet 400 mg (extended release)

omit:

	Nevirapine XR APOTEX	C4454 C4526	60	5
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[22] Schedule 1, entry for Ribavirin

insert as first entry:

Tablet 200 mg	Oral	lbavyr	C5957	200	2
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[23] Schedule 1, entry for Sildenafil

- (a) omit from the column headed "Circumstances" (all instances): **C10228 C10234 C10304**
- (b) omit from the column headed "Circumstances" (all instances): **C11340**
- (c) omit from the column headed "Circumstances" (all instances): **C11352**
- (d) insert in numerical order in the column headed "Circumstances" (all instances): **C12430 C12431 C12441 C12443 C12456**

[24] Schedule 1, entry for Tadalafil

(a) omit from the column headed “Circumstances” (all instances): **C10228 C10234 C10304**

(b) omit from the column headed “Circumstances” (all instances): **C11340**

(c) omit from the column headed “Circumstances” (all instances): **C11352**

(d) insert in numerical order in the column headed “Circumstances” (all instances): **C12430 C12431 C12441 C12443 C12456**

[25] Schedule 1, entry for Tocilizumab in the form Concentrate for injection 80 mg in 4 mL

insert in numerical order in the column headed “Circumstances”: **C12436 C12450 C12451**

[26] Schedule 1, entry for Tocilizumab in the form Concentrate for injection 200 mg in 10 mL

insert in numerical order in the column headed “Circumstances”: **C12436 C12450 C12451**

[27] Schedule 1, entry for Tocilizumab in the form Concentrate for injection 400 mg in 20 mL

insert in numerical order in the column headed “Circumstances”: **C12436 C12450 C12451**

[28] Schedule 2, Maximum quantities and repeats for certain HSD pharmaceutical benefits

substitute:

Schedule 2—Maximum quantities and repeats for certain HSD pharmaceutical benefits

Note: See sections 20 and 21, and the columns headed “Maximum quantity” and “Maximum repeats” in Schedule 1.

1 Maximum quantity or number of units and maximum number of repeats

The following table sets out the maximum quantity or number of units, and the maximum number of repeats, for prescribing HSD pharmaceutical benefits with the listed drugs, and in the circumstances, mentioned in the table.

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
Abatacept	C8638 C11806	1 dose	Sufficient for treatment for 16 weeks
	C8748 C11795	1 dose	4
	C12384	1 dose	5
	C8627 C8655 C12372 C12375	1 dose	Sufficient for treatment for 24 weeks
Adalimumab	C12111 C12117 C12120 C12169	2 doses	3
	C11526 C12112 C12114 C12116 C12166 C12355 C12373	2 doses	5
Ambrisentan	C11229 C11312 C11313 C11314 C12433 C12446 C12447 C12460	Sufficient for treatment for 1 month	5
Azacitidine	C6132 C6143 C6177 C12439	14 units	2
	C6144 C6186 C6199	14 units	5
Benralizumab	C11841 C11892 C11893	1	Sufficient for 32 weeks of treatment
	C11842	1	Sufficient for 24 weeks of treatment
Bosentan	C11229 C11312 C11313 C11314 C12406 C12423 C12427 C12458	Sufficient for treatment for 1 month	5
	C12425	Sufficient for treatment for 1 month	0
Dupilumab	C11844 C11897 C11926 C11964	1 pack	Sufficient for 32 weeks of treatment
	C11901 C11924 C11925	1 pack	Sufficient for 24 weeks of treatment
Eculizumab	C6626	1	Sufficient for 4 weeks of treatment

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
	C6642	1	4
	C6668 C6686 C6687 C6688	1	5
	C6637	1	6
Eltrombopag	C11199 C11202 C11244 C11262 C11263	1 pack	5
Epoprostenol	C11322 C11323 C11329 C11330 C11345 C11356 C12411 C12454	Sufficient for treatment for 1 month	5
Etanercept	C9417 C10548 C10578 C10599	Sufficient for treatment for 4 weeks	3
	C9384 C10579 C12357 C12407	Sufficient for treatment for 4 weeks	5
Iloprost	C10229 C11322 C11323 C11325 C11343 C11345 C11356 C11365	Sufficient for treatment for 1 month	5
Infliximab	C8800 C8886 C8983 C9110 C9111 C9169 C9191 C9400 C9401 C9402 C9487 C9558 C9559 C9587 C9877 C9994 C11094 C11095 C11111 C11112 C11127 C11128 C11129 C11158 C11159	1 dose of 5 mg per kg of patient weight	3
	C8646 C12024 C12039 C12061 C12361	1 dose of 3 mg per kg of patient weight	3
	C8745 C8844 C8940 C9188 C9472 C9481 C9584 C9602 C9621 C9668 C12004 C12058 C12067 C12075 C12362	1 dose of 3 mg per kg of patient weight	2
	C7777 C8296 C8881 C8883 C8941 C8962 C9065 C9067 C9068 C9669 C9677 C9719 C9721 C9732 C9751 C9752 C9754 C9775 C9779 C9783 C9787 C9799 C9803 C9900 C12003 C12007 C12025 C12042 C12043 C12049 C12051 C12059 C12063 C12069 C12074 C12076 C12313	1 dose of 5 mg per kg of patient weight	2
	C4524 C9632	5 vials	1
Ivacaftor	C9889 C9890	1 pack	Sufficient for 24 weeks of treatment
Lenalidomide	C10452 C10453	14 tablets	3
	C4282 C4287 C10428	21 tablets	3
	C10429	21 tablets	1
	C10349 C10350 C10373 C10427	21 tablets	5
	C10334 C10335	28 tablets	2
Lumacaftor with Ivacaftor	C9857 C9891 C9920 C9943 C10005 C10007	1 pack	5

Maximum quantity or number of units, and maximum number of repeats

Listed drug	Circumstances	Maximum quantity	Maximum repeats
Macitentan	C11229 C11312 C11313 C11314 C12402 C12403 C12420 C12463	Sufficient for treatment for 1 month	5
Mepolizumab	C11841 C11848 C11950	1	Sufficient for 32 weeks of treatment
	C11842	1	Sufficient for 24 weeks of treatment
Midostaurin	C11699 C11801 C11814	1 pack	2
Nusinersen	C12037	1 dose	0
	C11058 C12017	1 dose	3
Omalizumab	C7055	2	2
	C7046	2	5
	C10226 C11847	1	Sufficient for 24 weeks of treatment
	C10223 C10265	1	6
	C11841 C11846 C11902	1	Sufficient for 32 weeks of treatment
Pasireotide	C9088 C9089	2	5
Pegvisomant	C7087 C9041	1	5
Pomalidomide	C7791 C7952	1 pack (21 capsules)	5
	C12256 C12283	1 pack (14 capsules)	2
Riociguat	C6664	Sufficient for treatment for 1 month	3
	C10243 C10245	Sufficient for treatment for 1 month	4
	C6645 C7629 C10231	Sufficient for treatment for 1 month	5
Risdiplam	C11995 C11996	1	0
	C12057	1	5
Rituximab	C7021 C7022 C9340 C9344 C9448 C9450 C9511 C11749 C11812	2 doses	Sufficient for treatment for 4 weeks
	C12379	2 doses	0
	C9446 C9611	2 doses	1
	C9336 C9539 C9640 C9641	3 doses	5

Maximum quantity or number of units, and maximum number of repeats

Listed drug	Circumstances	Maximum quantity	Maximum repeats
Romiplostim	C11205 C11266	1 dose	4
	C11246 C11267 C11289	1 dose	5
Sildenafil	C11229 C11319 C11338 C11350 C12430 C12431 C12441 C12443 C12456	Sufficient for treatment for 1 month	5
Tadalafil	C11229 C11319 C11338 C11350 C12430 C12431 C12441 C12443 C12456	Sufficient for treatment for 1 month	5
Teduglutide	C12186 C12308 C12345	1 pack	5
	C11999 C12146	1 pack	11
Tezacaftor with Ivacaftor and Ivacaftor	C9880 C9961 C10064 C10069	1 pack	5
Tocilizumab	C8635 C8638 C9386 C9407 C9417 C9494 C10541 C10545 C10616 C11752 C11782 C12163 C12436 C12450 C12451	1 infusion	3
	C10532 C10535 C10567 C10570	2 infusions	3
	C8627 C8637 C9380 C9384 C9495 C10542	1 infusion	5
	C10536 C10571	2 infusions	5
Ustekinumab	C9655 C9656 C9710	4 vials (130 mg each)	0
Vedolizumab	C12080 C12083 C12135 C12137 C12179 C12219 C12220 C12221	1	2
	C9738 C9771	1	Sufficient for treatment for 24 weeks

[29] Schedule 3, entry for Ambrisentan

(a) omit:

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.</p>	Compliance with Authority Required procedures
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			A maximum of 5 repeats may be requested.	
	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: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form</p>	Compliance with Authority Required procedures

			<p>which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and (ii) ECHO composite assessment; and (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; (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:</p> <p>(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.</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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(b) *omit:*

	C11321		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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
	C11354		<p>Pulmonary arterial hypertension (PAH) Grandfathered patient (dual therapy)</p> <p>Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 December</p>	Compliance with Authority Required procedures

		<p>2020; AND</p> <p>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).</p> <p>(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.</p> <p>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.</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 was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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>	
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			A maximum of 5 repeats may be requested.	
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(c) insert in numerical order after existing text:

	C12433		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. 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
	C12446		<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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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

	C12447	<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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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
	C12460	<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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Patient must have 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) 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;</p>	Compliance with Written Authority Required procedures

			<p>(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 Azacitidine

insert in numerical order after existing text:

	C12439		<p>Acute Myeloid Leukaemia The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).</p>	Compliance with Authority Required procedures
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[31] Schedule 3, entry for Bosentan

(a) *omit:*

	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
	C10238		<p>Pulmonary arterial hypertension (PAH) Cessation of treatment (all patients) Patient must be receiving PBS-subsidised treatment with this PAH agent; AND</p>	Compliance with Authority Required procedures

			<p>The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.</p>	
	C10924		<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. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.</p>	Compliance with Authority Required procedures
	C10945		<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.</p>	Compliance with Written Authority Required procedures

		<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) two completed authority prescription forms; 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. The test results provided must not be more than 2 months old at the time of application.</p> <p>If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.</p> <p>Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.</p>	
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(b) omit:

	C11317	<p>Pulmonary arterial hypertension (PAH) Grandfathered patient (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October</p>	Compliance with Written Authority Required procedures
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		<p>2020; AND</p> <p>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).</p> <p>(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.</p> <p>(ii) A PDE-5i includes sildenafil citrate, or tadalafil.</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 was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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>	
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			A maximum of 5 repeats may be requested.	
	C11321		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. 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

(c) insert in numerical order after existing text:

	C12406		<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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product</p>	Compliance with Authority Required procedures
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		Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.	
	C12423	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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C12425	Pulmonary arterial hypertension (PAH) Cessation of treatment (all patients) Patient must be receiving PBS-subsidised treatment with this PAH agent; AND The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.	Compliance with Authority Required procedures
	C12427	Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Patient must 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	Compliance with Written Authority Required procedures

		<p>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) two completed authority prescription forms; 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>If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.</p> <p>Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information</p>	
	C12458	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be</p>	Compliance with Authority Required procedures

			<p>completed by the physician with expertise in PAH.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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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[32] Schedule 3, entry for Epoprostenol

(a) omit:

	C10241		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition 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>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 (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>	Compliance with Authority Required procedures
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(b) omit:

	C11325		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</p> <p>For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a</p>	Compliance with Authority Required procedures
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			<p>prostanoid is one of: (c) epoprostenol, (d) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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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(c) *insert in numerical order after existing text:*

	C12411		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change)</p> <p>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.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</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 (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>	Compliance with Authority Required procedures
	C12454		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease</p>	Compliance with Authority Required procedures

			<p>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>	
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[33] Schedule 3, entry for Etanercept

(a) *omit:*

	C12358		<p>Severe active juvenile idiopathic arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be under 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse</p>	Compliance with Written Authority Required procedures
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			<p>reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p> <p>If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.</p>	
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(b) *insert in numerical order after existing text:*

	C12407		<p>Severe active juvenile idiopathic arthritis</p> <p>First continuing treatment - Critical shortage of tocilizumab - Temporary listing</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p>	Compliance with Written Authority Required procedures
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			<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p> <p>If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.</p>	
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[34] Schedule 3, entry for Macitentan

(a) *omit:*

	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</p>	Compliance with Authority Required procedures

		<p>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.</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>	
	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: (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.</p>	Compliance with Written Authority Required procedures

		<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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(b) omit:

	C11317	<p>Pulmonary arterial hypertension (PAH) Grandfathered patient (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020; AND Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT;</p>	Compliance with Written Authority Required procedures
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			<p>(3) RHC composite assessment only.</p> <p>In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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>	
	C11321		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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

(c) insert in numerical order after existing text:

	C12402		<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.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; 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</p>	Compliance with Written Authority Required procedures
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		<p>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>	
	C12403	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures

		<p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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>	
	C12420	<p>Pulmonary arterial hypertension (PAH) 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>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</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
	C12463	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition 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>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</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 (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</p>	Compliance with Authority Required procedures

			the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
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[35] Schedule 3, entry for Sildenafil

(a) omit:

	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)</p>	Compliance with Written Authority Required procedures

		<p>agent; AND</p> <p>Patient must have been assessed by a physician with expertise in the management of PAH; AND</p> <p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; 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>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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(b) omit:

	C11340	<p>Pulmonary arterial hypertension (PAH) 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised Patient must have been receiving non-PBS subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with an endothelin receptor antagonist, where each agent was non-PBS subsidised, prior to 1 October 2020; OR Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be lodged either electronically or via mail/postal service and include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form</p>	Compliance with Written Authority Required procedures
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		<p>which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).</p> <p>Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</p> <p>(1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.</p> <p>In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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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(c) omit:

	C11352	<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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
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(d) insert in numerical order after existing text:

	C12430	<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. 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
	C12431	<p>Pulmonary arterial hypertension (PAH) 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin</p>	Compliance with Written Authority Required procedures

		<p>receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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 lodged either electronically or via mail/postal service and include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application 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 was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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>	
	C12441	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (new patients)</p>	<p>Compliance with Written Authority Required procedures</p>

		<p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; 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>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>	
	C12443	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (change)</p>	<p>Compliance with Authority Required procedures</p>

		<p>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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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>	
	C12456	<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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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

[36] Schedule 3, entry for Tadalafil

(a) *omit:*

	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</p>	Compliance with Authority Required procedures
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		<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>	
	C10234	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change)</p> <p>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</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>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>	Compliance with Authority Required procedures
	C10304	<p>Pulmonary arterial hypertension (PAH) 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 with expertise in the management of PAH; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; 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>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</p>	Compliance with Written Authority Required procedures

		<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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(b) omit:

	C11340	<p>Pulmonary arterial hypertension (PAH)</p> <p>'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised</p> <p>Patient must have been receiving non-PBS subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with an endothelin receptor antagonist, where each agent was non-PBS subsidised, prior to 1 October 2020; OR</p> <p>Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND</p> <p>The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR</p> <p>The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; AND</p>	Compliance with Written Authority Required procedures
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		<p>Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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 lodged either electronically or via mail/postal service and include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application 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 was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why</p>	
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			<p>the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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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(c) omit:

	C11352		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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
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(d) insert in numerical order after existing text:

	C12430		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan,</p>	Compliance with Authority Required procedures
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		<p>(c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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>	
	C12431	<p>Pulmonary arterial hypertension (PAH)</p> <p>'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised</p> <p>Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND</p> <p>The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR</p> <p>The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; AND</p> <p>Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</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>	Compliance with Written Authority Required procedures

		<p>Applications for authorisation must be lodged either electronically or via mail/postal service and include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application 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 was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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>	
	C12441	<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.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; 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>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</p>	Compliance with Written Authority Required procedures

		<p>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>	
	C12443	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition 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>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</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 (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,</p>	Compliance with Authority Required procedures

			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.	
	C12456		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. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures

[37] Schedule 3, entry for Tocilizumab

insert in numerical order after existing text:

	C12436		Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence	Compliance with Written Authority Required procedures
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		<p>demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C12450	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND</p> <p>Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p>	
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			If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C12451		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND</p> <p>Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</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 authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.</p> <p>If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p> <p>An adequate response to treatment is defined as:</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of</p>	Compliance with Written Authority Required procedures

			<p>response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
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