



PB 114 of 2022

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2022

National Health Act 1953

I, NIKOLAI TSYGANOV, Assistant Secretary (Acting), Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Date 30 November 2022

NIKOLAI TSYGANOV
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division

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1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2022*.
- (2) This instrument may also be cited as PB 114 of 2022.

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 2022</i>	<i>1 December 2022</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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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] Part 1, Division 1, Section 6, definition for “CAR drug”

substitute:

CAR drug (short for Complex Authority Required drug) means any of the following highly specialised drugs:

- (a) abatacept;
- (b) adalimumab;
- (c) ambrisentan;
- (d) azacitidine;
- (e) benralizumab;
- (f) bosentan;
- (g) burosumab;
- (h) dupilumab;
- (i) eculizumab;
- (j) elexacaftor with tezacaftor and with ivacaftor, and ivacaftor;
- (k) eltrombopag;
- (l) epoprostenol;
- (m) etanercept;
- (n) iloprost;
- (o) infliximab;
- (p) ivacaftor;
- (q) lenalidomide;
- (r) lumacaftor with ivacaftor;
- (s) macitentan;
- (t) mepolizumab;
- (u) midostaurin;

- (v) nusinersen;
- (w) omalizumab;
- (x) onasemnogene abeparvovec;
- (y) pasireotide;
- (z) pegcetacoplan;
- (aa) pegvisomant;
- (bb) pomalidomide;
- (cc) ravulizumab;
- (dd) riociguat;
- (ee) risdiplam;
- (ff) romiplostim;
- (gg) selexipag;
- (hh) sildenafil;
- (ii) tadalafil;
- (jj) teduglutide;
- (kk) tezacaftor with ivacaftor and ivacaftor;
- (ll) tocilizumab;
- (mm) ustekinumab;
- (nn) vedolizumab.

[2] 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): C11312 C11313 C11314 C12433 C12446 C12447 C12460

(b) insert in numerical order in the column headed "Circumstances" (all instances): C13496 C13497 C13499 C13500 C13575 C13576 C13580 C13582

[3] Schedule 1, entry for Benralizumab

omit:

Injection 30 mg in 1 mL single dose pre-filled syringe	Injection	Fasenra	C11841 C11842 C11892 C11893	See Schedule 2	See Schedule 2
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[4] Schedule 1, entry for Bosentan in the form Tablet 62.5 mg (as monohydrate)

(a) omit from the column headed "Circumstances" (all instances): **C11312 C11313 C11314 C12406 C12423**

(b) omit from the column headed "Circumstances" (all instances): **C12427 C12458**

(c) insert in numerical order in the column headed "Circumstances" (all instances): **C13495 C13496 C13497 C13499 C13571 C13580 C13582 C13632**

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

(a) omit from the column headed "Circumstances" (all instances): **C11312 C11313 C11314 C12406 C12423 C12427 C12458**

(b) insert in numerical order in the column headed "Circumstances" (all instances): **C13495 C13496 C13497 C13499 C13571 C13580 C13582 C13632**

[6] Schedule 1, entry for Eculizumab

(a) omit from the column headed "Circumstances": **C12944 C12945 C12953 C12954 C12955 C12964 C12969**

(b) insert in numerical order in the column headed "Circumstances": **C13458 C13459 C13461 C13464 C13560 C13619 C13660 C13661 C13684**

[7] Schedule 1, entry for Epoprostenol

substitute:

Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection	EPOPROSTENOL SUN	C13491 C13492 C13505 C13506 C13510 C13512 C13577 C13634	See Schedule 2	See Schedule 2
			Veletri	C13491 C13492 C13505 C13506 C13510 C13512 C13577 C13634	See Schedule 2	See Schedule 2
	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection	Flolan	C13491 C13492 C13505 C13506 C13510 C13512 C13577 C13634	See Schedule 2	See Schedule 2
	Powder for I.V. infusion 1.5 mg (as sodium)	Injection	EPOPROSTENOL SUN	C13491 C13492 C13505 C13506 C13510 C13512 C13577 C13634	See Schedule 2	See Schedule 2
			Veletri	C13491 C13492 C13505 C13506	See Schedule 2	See Schedule 2

				C13510 C13512 C13577 C13634		
Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection	Flolan		C13491 C13492 C13505 C13506 C13510 C13512 C13577 C13634	See Schedule 2	See Schedule 2

[8] Schedule 1, entry for Iloprost

omit from the column headed "Circumstances": **C10229 C11322 C11323 C11325 C11343 C11345 C11356 C11365** *substitute:* **C13491 C13492
C13505 C13506 C13510 C13577 C13631 C13634**

[9] Schedule 1, entry for Infliximab

substitute:

Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	C4524 C7777 C8296 C8646 C8745 C8844 C8881 C8883 C8886 C8940 C8941 C8962 C9065 C9067 C9068 C9111 C9188 C9400 C9402 C9472 C9481 C9487 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9677 C9719 C9721 C9732 C9751 C9754 C9775 C9779 C9783 C9787 C9803 C11158 C12003 C12004 C12025 C12039 C12042 C12043 C12049 C12051 C12058 C12059 C12063 C12067	See Schedule 2	See Schedule 2
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		C12069 C12074 C12075 C12313 C12361 C12362 C13518 C13522 C13526 C13529 C13584 C13586 C13587 C13589 C13590 C13591 C13592 C13639 C13640 C13641 C13679 C13689 C13691 C13692 C13702 C13705 C13706 C13714 C13715 C13719		
	Remicade	C4524 C7777 C8296 C8646 C8745 C8881 C8883 C8886 C8941 C8962 C9065 C9067 C9068 C9111 C9400 C9402 C9487 C9559 C9587 C9632 C9669 C9677 C9719 C9721 C9751 C9754 C9779 C9783 C9803 C11158 C12003 C12004 C12025 C12039 C12043 C12049 C12058 C12059 C12063 C12313 C12361 C12362 C13518 C13522 C13526 C13529 C13584 C13586 C13587 C13589 C13590 C13591 C13592 C13639 C13640 C13641	See Schedule 2	See Schedule 2

	C13679 C13689 C13691 C13692 C13702 C13705 C13706 C13714 C13715 C13719		
Renflexis	C4524 C7777 C8296 C8646 C8745 C8844 C8881 C8883 C8886 C8940 C8941 C8962 C9065 C9067 C9068 C9111 C9188 C9400 C9402 C9472 C9481 C9487 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9677 C9719 C9721 C9732 C9751 C9754 C9775 C9779 C9783 C9787 C9803 C11158 C12003 C12004 C12025 C12039 C12042 C12043 C12049 C12051 C12058 C12059 C12063 C12067 C12069 C12074 C12075 C12313 C12361 C12362 C13518 C13522 C13526 C13529 C13584 C13586 C13587 C13589 C13590 C13591 C13592 C13639 C13640 C13641 C13679 C13689	See Schedule 2	See Schedule 2

C13691 C13692
 C13702 C13705
 C13706 C13714
 C13715 C13719

[10] Schedule 1, entry for Macitentan

(a) omit from the column headed "Circumstances": **C11312 C11313 C11314 C12402 C12403 C12420 C12463**

(b) insert in numerical order in the column headed "Circumstances": **C13496 C13497 C13499 C13500 C13575 C13576 C13580 C13582**

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

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

Noumed Mycophenolate	C5554 C5795 C9691 C9693	300	5
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[12] Schedule 1, entry for Natalizumab

omit from the column headed "Circumstances": **C9744 C9818** substitute: **C13625 C13718**

[13] Schedule 1, after entry for Pasireotide in the form Injection (modified release) 60 mg (as embonate), vial and diluent syringe

insert:

Pegcetacoplan	Solution for subcutaneous infusion 1,080 mg in Injection 20 mL	Empaveli	C13616 C13655 C13658 C13710 C13743	See Schedule 2	See Schedule 2
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[14] Schedule 1, entry for Ravulizumab in each of the forms: Solution concentrate for I.V. infusion 300 mg in 3 mL; and Solution concentrate for I.V. infusion 1,100 mg in 11 mL

omit from the column headed "Circumstances": **C12950 C12958 C12959 C12967 C12970 C12973** substitute: **C13456 C13459 C13465 C13466 C13614 C13620 C13695**

[15] Schedule 1, entry for Riociguat in each of the forms: Tablet 500 micrograms; Tablet 1 mg; Tablet 1.5 mg; Tablet 2 mg; and Tablet 2.5 mg

(a) omit from the column headed "Circumstances": **C10231 C10243 C10245**

(b) insert in numerical order in the column headed "Circumstances": **C13502 C13514 C13515**

[16] Schedule 1, entry for Sildenafil

(a) omit from the column headed "Circumstances" (all instances): **C11319 C11338 C11350 C12430 C12431 C12441 C12443 C12456**

(b) insert in numerical order in the column headed "Circumstances" (all instances): **C13482 C13484 C13569 C13570 C13572 C13573 C13629 C13671**

[17] Schedule 1, entry for Tadalafil

(a) omit from the column headed "Circumstances" (all instances): **C11319 C11338 C11350 C12430 C12431 C12441 C12443 C12456**

(b) insert in numerical order in the column headed "Circumstances" (all instances): **C13482 C13484 C13569 C13570 C13572 C13573 C13629 C13671**

[18] Schedule 1, entry for Valganciclovir in the form Tablet 450 mg (as hydrochloride)

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

	Valganciclovir Viatrix	C4980 C4989 C9316	120	5
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[19] Schedule 2, entry for Ambrisentan

substitute:

Ambrisentan	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13580 C13582	Sufficient for treatment for 1 month	5
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[20] Schedule 2, entry for Bosentan

substitute:

Bosentan	C11229 C13495 C13496 C13497 C13499 C13571 C13580 C13582 C13632	Sufficient for treatment for 1 month	5
	C12425	Sufficient for treatment for 1 month	0

[21] Schedule 2, entry for Eculizumab

substitute:

Eculizumab	C6626	1	Sufficient for 4 weeks of treatment
	C6642	1	4
	C6668 C6686 C6687 C6688	1	5
	C6637	1	6

C13461	1	0
C13464 C13619 C13660 C13661 C13684	6	5
C13458 C13459 C13560	8	0

[22] Schedule 2, entry for Epoprostenol

substitute:

Epoprostenol	C13491 C13492 C13505 C13506 C13510 C13512 C13577 C13634	Sufficient for treatment for 1 month	5
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[23] Schedule 2, entry for Iloprost

substitute:

Iloprost	C13491 C13492 C13505 C13506 C13510 C13577 C13631 C13634	Sufficient for treatment for 1 month	5
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[24] Schedule 2, entry for Infliximab

substitute:

Infliximab	C8886 C9111 C9400 C9402 C9487 C9559 C9587 C11158 C13518 C13529 C13584 C13586 C13587 C13589 C13590 C13591 C13592 C13640 C13679 C13689 C13692 C13705 C13706 C13715 C13719	1 dose of 5 mg per kg of patient weight	3
	C8646 C12039 C12361 C13522 C13714	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 C9754 C9775 C9779 C9783 C9787 C9803 C12003 C12025 C12042 C12043 C12049 C12051 C12059 C12063 C12069 C12074 C12313 C13526 C13639 C13641 C13691 C13702	1 dose of 5 mg per kg of patient weight	2
	C4524 C9632	5 vials	1

[25] Schedule 2, entry for Macitentan*substitute:*

Macitentan	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13580 C13582	Sufficient for treatment for 1 month	5
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[26] Schedule 2, after entry for Pasireotide*insert:*

Pegcetacoplan	C13655 C13710	Sufficient for treatment for 4 weeks	0
	C13616 C13658 C13743	Sufficient for treatment for 4 weeks	5

[27] Schedule 2, entry for Ravulizumab*substitute:*

Ravulizumab	C13456 C13459 C13614 C13620	1 dose	0
	C13465 C13466 C13695	1 dose	2

[28] Schedule 2, entry for Riociguat*substitute:*

Riociguat	C6664	Sufficient for treatment for 1 month	3
	C13514 C13515	Sufficient for treatment for 1 month	4
	C6645 C7629 C13502	Sufficient for treatment for 1 month	5

[29] Schedule 2, entry for Sildenafil*substitute:*

Sildenafil	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629 C13671	Sufficient for treatment for 1 month	5
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[30] Schedule 2, entry for Tadalafil*substitute:*

Tadalafil	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629 C13671	Sufficient for treatment for 1 month	5
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[31] Schedule 3, entry for Ambrisentan

substitute:

Ambrisentan	C11229	<p>Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'). Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The authority application for selexipag must be approved prior to the authority application for this agent. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
	C13496	<p>Pulmonary arterial hypertension (PAH) Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p>	Compliance with Written Authority Required procedures

		<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 endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary</p>	
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			hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The test results must not be more than 6 months old at the time of application.	
	C13497		Pulmonary arterial hypertension (PAH) Initial 3 - changing to this drug in combination therapy (dual or triple therapy) 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 endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. 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; AND Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.	Compliance with Authority Required procedures
	C13499		Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) 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 endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. 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; AND Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.	Compliance with Authority Required procedures
	C13500		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) 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 not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; 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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities	Compliance with Written Authority Required procedures

		<p>System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 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. A maximum of 5 repeats may be requested.</p>	
	C13575	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH</p>	<p>Compliance with Authority Required procedures</p>

			<p>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>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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>	
	C13576		<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, 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>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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
	C13580		<p>Pulmonary arterial hypertension (PAH)</p> <p>Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy</p>	Compliance with Authority Required procedures

		<p>consisting of one endothelin receptor antagonist with one prostanoid, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; OR Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND</p> <p>The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; OR</p> <p>The condition must have, at the time non-PBS combination therapy was initiated, been both: (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and (b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion</p>	
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			<p>from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
	C13582		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; 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: (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 endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.</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

[32] Schedule 3, entry for Bosentan

substitute:

Bosentan	C11229		<p>Pulmonary arterial hypertension (PAH)</p> <p>Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR</p> <p>The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').</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
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		<p>The authority application for selexipag must be approved prior to the authority application for this agent.</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>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>The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.</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. A maximum of 5 repeats may be requested.</p>	
	C12425	<p>Pulmonary arterial hypertension (PAH)</p> <p>Cessation of treatment (all patients)</p> <p>Patient must be receiving PBS-subsidised treatment with this PAH agent; AND</p> <p>The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy.</p> <p>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 maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.</p>	Compliance with Authority Required procedures
	C13495	<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, 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>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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</p>	Compliance with Authority Required procedures

			<p>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>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>	
	C13496		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; 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 endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p>	Compliance with Written Authority Required procedures

		<p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 months old at the time of application.</p>	
	C13497	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</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 endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</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; AND</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.</p>	Compliance with Authority Required procedures
	C13499	<p>Pulmonary arterial hypertension (PAH)</p>	Compliance with Authority

			<p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) 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 endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. 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; AND Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.</p>	Required procedures
	C13571		<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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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
	C13580		<p>Pulmonary arterial hypertension (PAH) Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one prostanoid, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; OR Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; OR The condition must have, at the time non-PBS combination therapy was initiated, been both: (i)</p>	Compliance with Authority Required procedures

		<p>classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
	C13582	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application</p>	Compliance with Authority Required procedures

		<p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; 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: (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 endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.</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>	
	C13632	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (new patients)</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must have 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>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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) 	Compliance with Written Authority Required procedures

		<p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 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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[33] Schedule 3, entry for Burosumab

substitute:

Burosumab	C13330	<p>X-linked hypophosphataemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved normalisation in serum phosphate levels; AND Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.</p>	Compliance with Authority Required procedures
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			<p>Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist. Where adequate response to treatment with this drug cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p>	
	C13377		<p>X-linked hypophosphataemia Initial treatment - New patient</p> <p>Patient must have a documented confirmation of PHEX pathogenic variant; OR</p> <p>Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.</p> <p>Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures
	C13400		<p>X-linked hypophosphataemia Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2022; AND</p> <p>Patient must have a documented confirmation of PHEX pathogenic variant; OR</p> <p>Patient must have, prior to commencing non-PBS-subsidised supply, a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range;</p>	Compliance with Authority Required procedures

		<p>(iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine; AND Patient must have achieved normalisation in serum phosphate levels; AND Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion. Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist. Where adequate response to treatment with this drug cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p>	
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[34] Schedule 3, entry for Eculizumab

(a) *omit:*

	C12944	<p>Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria; AND The treatment must not be in combination with ravulizumab. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets ($\times 10^9/L$) (iii) White Cell Count ($\times 10^9/L$) (iv) Reticulocytes ($\times 10^9/L$) (v) Neutrophils ($\times 10^9/L$) (vi) Granulocyte clone size (%)</p>	Compliance with Written Authority Required procedures
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			(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory (viii) Multiple of LDH , ULN	
	C12945		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 2 (transition from LSDP-funded eculizumab) Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have demonstrated clinical improvement or stabilisation of condition; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must not be in combination with ravulizumab. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p>	Compliance with Written Authority Required procedures

			<p>(i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory (viii) Multiple of LDH , ULN</p>	
	C12953		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 1 (new patient) induction doses Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must not be in combination with ravulizumab. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L)</p>	Compliance with Written Authority Required procedures

			(ii) Platelets (x10 ⁹ /L) (iii) White Cell Count (x10 ⁹ /L) (iv) Reticulocytes (x10 ⁹ /L) (v) Neutrophils (x10 ⁹ /L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory (viii) Multiple of LDH , ULN	
	C12954		Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria; AND Patient must have demonstrated clinical improvement or stabilisation of condition; AND The treatment must not be in combination with ravulizumab. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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).	Compliance with Written Authority Required procedures
	C12955		Paroxysmal nocturnal haemoglobinuria (PNH) Balance of Supply (transition from non-PBS-subsidised treatment during induction phase) Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have received insufficient quantity to complete the induction treatment phase; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal	Compliance with Written Authority Required procedures

		<p>activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with ravulizumab.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</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>At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory</p> <p>(viii) Multiple of LDH , ULN</p>	
	C12964	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)</p> <p>Patient must be planning pregnancy; OR</p> <p>Patient must be pregnant; AND</p> <p>Patient must have received PBS-subsidised treatment with ravulizumab for this condition; AND</p> <p>The treatment must not be in combination with ravulizumab.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</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>Patient may qualify under this treatment phase more than once. In the event of miscarriage,</p>	Compliance with Written Authority Required procedures

			patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.	
	C12969		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have demonstrated clinical improvement or stabilisation of condition; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must not be in combination with ravulizumab. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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). At the time of the authority application, details (result and date of result) of the following monitoring</p>	Compliance with Written Authority Required procedures

			<p>requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory</p> <p>(viii) Multiple of LDH , ULN</p>	
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(b) *insert in numerical order after existing text:*

	C13458		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)</p> <p>Patient must be planning pregnancy; OR</p> <p>Patient must be pregnant; AND</p> <p>Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND</p> <p>The treatment must not be in combination with any of (i) ravulizumab, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</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>Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	Compliance with Written Authority Required procedures
	C13459		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Return from PBS-subsidised pegcetacoplan - induction doses</p> <p>Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND</p> <p>Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND</p> <p>Patient must have developed resistance or intolerance to pegcetacoplan; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Written Authority Required procedures

			(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). For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.	
	C13461		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Balance of Supply (transition from non-PBS-subsidised treatment during induction phase) Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have received insufficient quantity to complete the induction treatment phase; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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</p>	Compliance with Written Authority Required procedures

		<p>latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <ul style="list-style-type: none"> (i) Haemoglobin (g/L) (ii) Platelets ($\times 10^9/L$) (iii) White Cell Count ($\times 10^9/L$) (iv) Reticulocytes ($\times 10^9/L$) (v) Neutrophils ($\times 10^9/L$) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5 	
	C13464	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing</p>	Compliance with Written Authority Required procedures

		<p>treatment with eculizumab; OR</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</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>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets ($\times 10^9/L$)</p> <p>(iii) White Cell Count ($\times 10^9/L$)</p> <p>(iv) Reticulocytes ($\times 10^9/L$)</p> <p>(v) Neutrophils ($\times 10^9/L$)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
	C13560	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - initial 1 (new patient) induction doses</p> <p>Patient must not have received prior treatment with this drug for this condition; AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND</p> <p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy;</p> <p>OR</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months;</p> <p>OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial</p>	Compliance with Written Authority Required procedures

		<p>hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
	C13619	<p>Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L)</p>	Compliance with Written Authority Required procedures

		<p>(iv) Reticulocytes ($\times 10^9/L$)</p> <p>(v) Neutrophils ($\times 10^9/L$)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
	C13660	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Grandfather 2 (transition from LSDP-funded eculizumab)</p> <p>Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND</p> <p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; OR</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to $60 \text{ mL/min/1.73m}^2$, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the</p>	Compliance with Written Authority Required procedures

			<p>patient's drug treatment details.</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>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets ($\times 10^9/L$)</p> <p>(iii) White Cell Count ($\times 10^9/L$)</p> <p>(iv) Reticulocytes ($\times 10^9/L$)</p> <p>(v) Neutrophils ($\times 10^9/L$)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
	C13661		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Subsequent Continuing Treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; OR</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</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>	Compliance with Written Authority Required procedures
	C13684		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)</p> <p>Patient must be planning pregnancy; OR</p> <p>Patient must be pregnant; AND</p> <p>Patient must have received PBS-subsidised treatment with ravulizumab for this condition; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p>	Compliance with Written Authority Required procedures

			<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>Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	
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[35] Schedule 3, entry for Epoprostenol

substitute:

Epoprostenol	C13491		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. 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. 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
	C13492		<p>Pulmonary arterial hypertension (PAH) Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy</p>	Compliance with Authority Required procedures

		<p>consisting of one endothelin receptor antagonist with one prostanoid, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; OR Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND</p> <p>The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; OR</p> <p>The condition must have, at the time non-PBS combination therapy was initiated, been both: (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion</p>	
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			from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C13505		Pulmonary arterial hypertension (PAH) Initial 3 - changing to this drug in combination therapy (dual or triple therapy) The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND 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.	Compliance with Authority Required procedures
	C13506		Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND 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.	Compliance with Authority Required procedures
	C13510		Pulmonary arterial hypertension (PAH) Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin	Compliance with Written Authority Required procedures

		<p>receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 months old at the time of application.</p>	
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	C13512	<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 WHO Functional Class IV PAH; 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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) 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). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is: - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. (3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p>	Compliance with Written Authority Required procedures
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			<p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 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 Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C13577		<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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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
	C13634		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (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 prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate. 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

[36] Schedule 3, entry for Iloprost

substitute:

Iloprost	C13491	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. 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. 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
	C13492	<p>Pulmonary arterial hypertension (PAH) Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one prostanoid, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; OR Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; OR</p>	Compliance with Authority Required procedures

		<p>The condition must have, at the time non-PBS combination therapy was initiated, been both: (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
	C13505	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one</p>	Compliance with Authority Required procedures

			<p>phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND</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>	
	C13506		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND</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
	C13510		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p>	Compliance with Written Authority Required procedures

		<p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 months old at the time of application.</p>	
	C13577	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>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,</p>	Compliance with Authority Required procedures

			<p>iloprost, 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>	
	C13631		<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 WHO Functional Class III drug and toxins induced 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>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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; 	Compliance with Written Authority Required procedures

		<p>- ECHO composite assessment only.</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 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 Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C13634	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH;</p> <p>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: (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 prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.</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

[37] Schedule 3, entry for Infliximab

(a) omit:

	C8800	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological</p>	Compliance with Written Authority Required
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		<p>medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	procedures
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(b) omit:

	C8983	<p>Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for</p>	Compliance with Written Authority Required procedures
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		<p>this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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 within this treatment cycle.</p>	
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(c) omit:

	C9110	Severe psoriatic arthritis	Compliance with Written
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		<p>Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (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). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment.</p>	<p>Authority Required procedures</p>
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			<p>This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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>	
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(d) *omit:*

	C9169		<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Major joints are defined as (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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints.</p> <p>Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p>	Compliance with Written Authority Required procedures
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		<p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</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 to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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>	
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(e) omit:

	C9191	<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p> <p>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and</p>	Compliance with Written Authority Required procedures
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		<p>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 major 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 quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</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 to the Department of Human Services 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> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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 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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(f) omit:

	C9401	Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of	Compliance with Written Authority Required
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		<p>more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Up to a maximum of 3 repeats will be authorised. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for</p>	procedures
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		<p>PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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>	
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(g) omit:

	C9558	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND</p> <p>Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND</p> <p>Patient must not receive more than 18 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND</p> <p>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but</p>	Compliance with Written Authority Required procedures
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		<p>prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.</p> <p>Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a completed BASDAI Assessment Form; and</p> <p>(iii) a completed Exercise Program Self Certification Form included in the supporting information form.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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>	
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(h) omit:

	C9752	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p>	Compliance with Written Authority Required procedures
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		<p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR</p> <p>Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and</p> <p>(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.</p> <p>The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p>	
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			<p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not provided within this 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>	
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(i) *omit:*

	C9799		<p>Moderate to severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 6 to 17 years inclusive. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for</p>	Compliance with Authority Required procedures
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			<p>sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not provided within this 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>	
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(j) omit:

	C9877		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of</p>	Compliance with Written Authority Required procedures
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		<p>treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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>	
	C9900	<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have an externally draining enterocutaneous or rectovaginal fistula.</p> <p>Applications for authorisation must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

		<p>(a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this 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>	
	C9994	<p>Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p>	Compliance with Written Authority Required procedures

		<p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</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>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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>	
	C11094	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</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>The PASI assessment for first continuing or subsequent continuing treatment must be performed</p>	
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		<p>on the same affected area as assessed at baseline.</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 within this treatment cycle.</p>	
	C11095	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</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>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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</p>	Compliance with Written Authority Required procedures

		<p>treatment.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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>	
	C11111	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.</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</p>	Compliance with Written Authority Required procedures

		<p>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 within this treatment cycle.</p>	
	C11112	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or</p>	Compliance with Written Authority Required procedures

		<p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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 within this treatment cycle.</p>	
	C11127	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this</p>	Compliance with Written Authority Required procedures

		<p>condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</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</p>	
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		<p>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 within this treatment cycle.</p>	
	C11128	<p>Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. 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. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p>	Compliance with Written Authority Required procedures

			<p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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>	
	C11129		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.</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</p>	Compliance with Written Authority Required procedures

		<p>who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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 within this treatment cycle.</p>	
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(k) omit:

	C11159	<p>Severe chronic plaque psoriasis Initial 1 - Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.</p>	Compliance with Written Authority Required procedures
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		<p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</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 within this treatment cycle.</p>	
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(l) omit:

	C12007	<p>Severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this</p>	Compliance with Written Authority Required procedures
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		<p>condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR</p> <p>Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have evidence of intestinal inflammation; OR</p> <p>Patient must be assessed clinically as being in a high faecal output state; OR</p> <p>Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iii) the date of the most recent clinical assessment.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no</p>	
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		<p>circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</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 within this treatment cycle. 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 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>	
	C12024	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p>	Compliance with Written Authority Required procedures

		<p>Patient must be aged 18 years or older.</p> <p>Major joints are defined as (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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.</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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(m) omit:

	C12061	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient)</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 not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to</p>	Compliance with Written Authority Required procedures
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		<p>achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR</p> <p>Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p>	
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		<p>(b) at least 4 active joints from the following list of major joints: (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). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of 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 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 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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(n) omit:

	C12076	<p>Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p>	Compliance with Written Authority Required procedures
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		<p>Patient must be aged 18 years or older.</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR</p> <p>Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR</p> <p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and</p> <p>(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iv) the date of the most recent clinical assessment.</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as</p>	
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		<p>the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</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>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</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 within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
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(o) insert in numerical order after existing text:

	C13518	<p>Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (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). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to an initial course of treatment must be conducted</p>	Compliance with Written Authority Required procedures
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			<p>following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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>	
	C13522		<p>Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Major joints are defined as (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). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p>	Compliance with Written Authority Required procedures

		<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.</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>	
	C13526	<p>Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be at least 18 years of age. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive</p>	Compliance with Written Authority Required procedures

		<p>months; OR</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months;</p> <p>AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR</p> <p>Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below;</p> <p>OR</p> <p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and</p> <p>(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iv) the date of the most recent clinical assessment.</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity</p>	
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		<p>necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</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>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</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 within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C13529	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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 within this treatment cycle.</p>	
	C13584	<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and</p>	Compliance with Written Authority Required procedures

		<p>tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (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). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. 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 to the Department of Human Services 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 the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. 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>	
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C13586		<p>Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	Compliance with Written Authority Required procedures
C13587		<p>Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand</p>	Compliance with Written Authority Required procedures

		<p>or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition. 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. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
	C13589	<p>Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the</p>	Compliance with Written Authority Required procedures

		<p>sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following: <ul style="list-style-type: none"> (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form. <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Up to a maximum of 3 repeats will be authorised. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. 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>	
	C13590	Severe chronic plaque psoriasis	Compliance with Written

		<p>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	Authority Required procedures
	C13591	<p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation</p>	
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		<p>sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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 within this treatment cycle.</p>	
	C13592	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p>	Compliance with Written Authority Required procedures

		<p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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>	
	C13639	<p>Severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology</p>	Compliance with Written Authority Required procedures

		<p>(code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be</p>	
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		<p>authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</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 within this treatment cycle. 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 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>	
	C13640	<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and</p>	Compliance with Written Authority Required procedures

		<p>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 major 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 quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</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 to the Department of Human Services 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> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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 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>	
	C13641	<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have an externally draining enterocutaneous or rectovaginal fistula. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of 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 reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C13679	<p>Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is</p>	Compliance with Written Authority Required procedures

		<p>sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</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>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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>	
	C13689	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND</p> <p>Patient must not receive more than 18 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND</p> <p>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.</p> <p>Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a completed BASDAI Assessment Form; and</p> <p>(iii) a completed Exercise Program Self Certification Form included in the supporting information form.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per</p>	
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		<p>kg.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</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>	
	C13691	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet</p>	Compliance with Authority Required procedures

		<p>including the date of assessment of the patient's condition which must be no more than one month old at the time of application.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</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>	
	C13692	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as:</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</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</p>	Compliance with Written Authority Required procedures

		<p>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>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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>	
	C13702	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR</p> <p>Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-</p>	Compliance with Written Authority Required procedures

		<p>mercaptopurine and methotrexate; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and</p> <p>(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.</p> <p>The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</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>	
	C13705	Severe chronic plaque psoriasis	Compliance with Written

		<p>Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of</p>	<p>Authority Required procedures</p>
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		<p>commencement and duration of therapy].</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>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 within this treatment cycle.</p>	
	C13706	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p>	Compliance with Written Authority Required procedures

		<p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</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>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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 within this treatment cycle.</p>	
	C13714	<p>Severe active rheumatoid arthritis Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid</p>	<p>Compliance with Written Authority Required procedures</p>

		<p>arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR</p> <p>Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated</p>	
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		<p>in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (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). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of 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 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 under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C13715	<p>Severe chronic plaque psoriasis Initial 1 - Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this</p>	Compliance with Written Authority Required procedures

		<p>condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p>	
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	C13719	<p>Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. 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</p>	Compliance with Written Authority Required procedures

			<p>who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</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>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration 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 within this treatment cycle.</p> <p>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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[38] Schedule 3, entry for Macitentan

substitute:

Macitentan	C11229		<p>Pulmonary arterial hypertension (PAH)</p> <p>Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR</p> <p>The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').</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 authority application for selexipag must be approved prior to the authority application for this agent.</p>	Compliance with Authority Required procedures
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	C13496	<p>Pulmonary arterial hypertension (PAH) Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; 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 endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with 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. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) 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). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right</p>	Compliance with Written Authority Required procedures

		<p>ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 months old at the time of application.</p>	
	C13497	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</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 endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</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; AND</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.</p>	Compliance with Authority Required procedures
	C13499	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</p>	Compliance with Authority Required procedures

			<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 endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</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; AND</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.</p>	
	C13500		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients)</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 not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</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>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; 	Compliance with Written Authority Required procedures

		<p>- RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 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>	
	C13575	<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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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
	C13576	<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.</p>	Compliance with Authority Required procedures

		<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>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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>	
	C13580	<p>Pulmonary arterial hypertension (PAH)</p> <p>Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one prostanoid, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; OR</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND</p> <p>The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; OR</p> <p>The condition must have, at the time non-PBS combination therapy was initiated, been both: (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>	Compliance with Authority Required procedures

		<p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT)</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only.</p> <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is: - ECHO composite assessment plus 6MWT; - ECHO composite assessment only.</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
	C13582	<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (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 endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin</p>	Compliance with Authority Required procedures

			<p>receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.</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>	
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[39] Schedule 3, entry for Natalizumab

substitute:

Natalizumab	C13625		<p>Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist. The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13625
	C13718		<p>Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist. The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13718

			patient is being treated with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.	
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[40] Schedule 3, after entry for Pasireotide

insert:

Pegcetacoplan	C13616		<p>Paroxysmal nocturnal haemoglobinuria (PNH) First continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND The treatment must not be in combination with a Complement 5 (C5) inhibitor. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 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). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p>	Compliance with Written Authority Required procedures
	C13655		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment (new patient) Patient must not have received prior treatment with this drug for this condition; AND Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months; AND Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor demonstrated by a haemoglobin level of less than 105 g/L; OR Patient must be intolerant to C5 inhibitors as determined by the treating physician; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred; AND</p> <p>The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>Patient must be at least 18 years of age.</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>At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets ($\times 10^9/L$)</p> <p>(iii) White Cell Count ($\times 10^9/L$)</p> <p>(iv) Reticulocytes ($\times 10^9/L$)</p> <p>(v) Neutrophils ($\times 10^9/L$)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p>	
	C13658	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Grandfathered treatment (transition from non-PBS-subsidised treatment after the initial 4 weeks of therapy)</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022; AND</p> <p>Patient must have a documented PNH granulocyte clone size equal to or greater than 10% within the 3 months prior to initiating non-PBS-subsidised treatment with this drug; AND</p> <p>Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor demonstrated by a haemoglobin level of less than 105 g/L prior to initiating non-PBS-subsidised treatment with this drug; OR</p> <p>Patient must be intolerant to C5 inhibitors as determined by the treating physician prior to initiating non-PBS-subsidised treatment with this drug; AND</p> <p>Patient must have been receiving treatment with at least one C5 inhibitor for at least 3 months prior to initiating non-PBS-subsidised treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred; AND</p> <p>The treatment must not be in combination with a Complement 5 (C5) inhibitor; AND</p> <p>Patient must have had at least the initial 4 weeks of pegcetacoplan treatment; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug.</p> <p>Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include:</p> <p>(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).</p> <p>At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L) (ii) Platelets ($\times 10^9/L$) (iii) White Cell Count ($\times 10^9/L$) (iv) Reticulocytes ($\times 10^9/L$) (v) Neutrophils ($\times 10^9/L$) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p>	
	C13710	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Return from PBS-subsidised eculizumab post pregnancy or from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy</p> <p>Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 3 (switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)' criteria; OR Patient must have received prior PBS-subsidised treatment with at least one C5 inhibitor and returning to pegcetacoplan treatment for reasons other than post pregnancy; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.</p> <p>Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Written Authority Required procedures

		<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>At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets ($\times 10^9/L$)</p> <p>(iii) White Cell Count ($\times 10^9/L$)</p> <p>(iv) Reticulocytes ($\times 10^9/L$)</p> <p>(v) Neutrophils ($\times 10^9/L$)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p> <p>For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.</p>	
	C13743	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Subsequent continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; OR</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>The treatment must not be in combination with a Complement 5 (C5) inhibitor.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>Patient must be at least 18 years of age.</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>At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Written Authority Required procedures

[41] Schedule 3, entry for Ravulizumab

substitute:

Ravulizumab	C13456	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised eculizumab - induction dose Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.</p>	Compliance with Written Authority Required procedures
	C13459	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised pegcetacoplan - induction doses Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND Patient must have developed resistance or intolerance to pegcetacoplan; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. 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). For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	Compliance with Written Authority Required procedures

	C13465	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.</p>	Compliance with Written Authority Required procedures
	C13466	<p>Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets ($\times 10^9/L$) (iii) White Cell Count ($\times 10^9/L$) (iv) Reticulocytes ($\times 10^9/L$)</p>	Compliance with Written Authority Required procedures

			<p>(v) Neutrophils ($\times 10^9/L$) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
	C13614		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 1 (new patient) induction dose Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information At the time of the authority application, details (result and date of result) of the following monitoring</p>	Compliance with Written Authority Required procedures

			<p>requirements must be provided:</p> <ul style="list-style-type: none"> (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5 	
	C13620		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets ($\times 10^9/L$) (iii) White Cell Count ($\times 10^9/L$) (iv) Reticulocytes ($\times 10^9/L$) (v) Neutrophils ($\times 10^9/L$) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
	C13695	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather (transition from non-PBS-subsidised treatment) Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab; AND Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR</p>	Compliance with Written Authority Required procedures

		<p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>Patient must be at least 18 years of age.</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>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
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[42] Schedule 3, entry for Riociguat

(a) omit:

	C10231	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p>	Compliance with Authority Required procedures
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			<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>	
	C10243		<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</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>Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	Compliance with Authority Required procedures
	C10245		<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</p> <p>Patient must have 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>	Compliance with Written Authority Required procedures

		<p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. 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> <ul style="list-style-type: none"> (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. <p>Applications for authorisation must be in writing and must include:</p> <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). <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> <ul style="list-style-type: none"> (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. <p>In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <ul style="list-style-type: none"> (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. <p>Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>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>Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	
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(b) insert in numerical order after existing text:

	C13502		<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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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
	C13514		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	Compliance with Authority Required procedures

	C13515	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) 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). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is: - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. (3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current. (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary</p>	Compliance with Written Authority Required procedures
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			<p>hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The test results must not be more than 6 months old at the time of application. Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	
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[43] Schedule 3, entry for Sildenafil

substitute:

Sildenafil	C11229		<p>Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'). Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The authority application for selexipag must be approved prior to the authority application for this agent. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written</p>	Compliance with Authority Required procedures
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			confirmation of the reasons why must also be included in the patient's medical record. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C13482		<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. 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. 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
	C13484		<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; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include:</p>	Compliance with Written Authority Required procedures

		<p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 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. A maximum of 5 repeats may be requested.</p>	
	C13569	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</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</p>	Compliance with Authority Required procedures

			<p>phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND</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>	
	C13570		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</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; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND</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
	C13572		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>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>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
	C13573		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH;</p>	Compliance with Authority Required procedures

		<p>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: (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; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.</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>	
	C13629	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; 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; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p>	Compliance with Authority Required procedures

		<ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
	C13671	<p>Pulmonary arterial hypertension (PAH)</p> <p>Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; OR</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND</p> <p>The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; OR</p> <p>The condition must have, at the time non-PBS combination therapy was initiated, been both: (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p>	Compliance with Authority Required procedures

			<p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and (b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT)</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only.</p> <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is: - ECHO composite assessment plus 6MWT; - ECHO composite assessment only.</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
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[44] Schedule 3, entry for Tadalafil

substitute:

Tadalafil	C11229		<p>Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR</p>	Compliance with Authority Required procedures
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	C13482	<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. 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. 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</p>	Compliance with Authority Required procedures

			<p>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>	
	C13484		<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; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) 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). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p>	Compliance with Written Authority Required procedures

		<p>- ECHO composite assessment plus 6MWT; - ECHO composite assessment only. (3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current. (5) Confirm that this authority application is not seeking subsidy for a patient 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 test results must not be more than 6 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>	
	C13569	<p>Pulmonary arterial hypertension (PAH) Initial 3 - changing to this drug in combination therapy (dual or triple therapy) 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; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND 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
	C13570	<p>Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) 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; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND Must be treated by a physician with expertise in the management of PAH, with this authority</p>	Compliance with Authority Required procedures

			application to be completed by the physician with expertise in PAH.	
	C13572		<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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, 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
	C13573		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (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; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate. 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
	C13629		<p>Pulmonary arterial hypertension (PAH) Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p>	Compliance with Authority Required procedures

		<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; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</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>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) 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>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
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	C13671	<p>Pulmonary arterial hypertension (PAH) Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; OR Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; OR The condition must have, at the time non-PBS combination therapy was initiated, been both: (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above. 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. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) 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). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p>	Compliance with Authority Required procedures
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		<p>- ECHO composite assessment plus 6MWT; - ECHO composite assessment only.</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient 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>	
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