



**PB 79 of 2024**

# **National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2024**

*National Health Act 1953*

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I, NIKOLAI TSYGANOV, Assistant Secretary, 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*.

Dated 30 July 2024

**NIKOLAI TSYGANOV**  
Assistant Secretary  
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 (August Update) Instrument 2024*.
- (2) This instrument may also be cited as PB 79 of 2024.

## 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 August 2024</i>	<i>1 August 2024</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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## 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) anifrolumab;
- (e) avatrombopag;
- (f) azacitidine;
- (g) benralizumab;
- (h) bosentan;
- (i) burosumab;
- (j) daunorubicin with cytarabine;
- (k) difelikefalin;
- (l) dupilumab;
- (m) eculizumab;
- (n) elexacaftor with tezacaftor and with ivacaftor, and ivacaftor;
- (o) eltrombopag;
- (p) epoprostenol;
- (q) etanercept;
- (r) iloprost;
- (s) infliximab;
- (t) ivacaftor;

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- (u) lenalidomide;
  - (v) lumacaftor with ivacaftor;
  - (w) macitentan;
  - (x) mepolizumab;
  - (y) midostaurin;
  - (z) nusinersen;
  - (aa) omalizumab;
  - (bb) onasemnogene abeparvovec;
  - (cc) pasireotide;
  - (dd) patisiran;
  - (ee) pegcetacoplan;
  - (ff) pegvisomant;
  - (gg) pomalidomide;
  - (hh) ravulizumab;
  - (ii) riociguat;
  - (jj) risdiplam;
  - (kk) romiplostim;
  - (ll) selexipag;
  - (mm) sildenafil;
  - (nn) tadalafil;
  - (oo) teduglutide;
  - (pp) tezacaftor with ivacaftor and ivacaftor;
  - (qq) tocilizumab;
  - (rr) ustekinumab;
  - (ss) vedolizumab.

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**[2] Schedule 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe**

*insert as first entry:*

	Abrilada	C12120 C14061 C14063 C14064 C14107 C14136	See Schedule 2	See Schedule 2
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**[3] Schedule 1, entry for Adalimumab in each of the forms: Injection 40 mg in 0.8 mL pre-filled pen; and Injection 40 mg in 0.8 mL pre-filled syringe**

*insert as first entry:*

	Abrilada	C12120 C14061 C14063 C14064 C14107 C14136	See Schedule 2	See Schedule 2
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**[4] Schedule 1, entry for Bosentan in the form Tablet 125 mg (as monohydrate)**

*omit:*

	Bosentan Cipla	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632	See Schedule 2	See Schedule 2
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**[5] Schedule 1, entry for Cinacalcet in the form Tablet 90 mg (as hydrochloride)**

*omit:*

	Cinacalcet Mylan	C10063 C10067 C10073	56	5
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**[6] Schedule 1, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor**

*substitute:*

Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	Pack containing 28 sachets containing granules elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets containing granules ivacaftor 59.5 mg	Oral	Trikafta	C15482 C15511	See Schedule 2	See Schedule 2
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Pack containing 28 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg	Oral	Trikafta	C15482 C15511	See Schedule 2	See Schedule 2
Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg	Oral	Trikafta	C13932 C13991	See Schedule 2	See Schedule 2
Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg	Oral	Trikafta	C13962 C13980	See Schedule 2	See Schedule 2

**[7] Schedule 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg**

*omit:*

CellCept	C5600 C5653 C9689 C9690	600	5
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**[8] Schedule 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg**

*omit:*

CellCept	C5554 C5795 C9691 C9693	300	5
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**[9] Schedule 1, entry for Onasemnogene abeparvovec**

*substitute:*

Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2

4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL						
Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460		See Schedule 2	See Schedule 2
Pack containing 2 vials solution for I.V. infusion	Injection	Zolgensma	C12639 C14468		See Schedule 2	See Schedule 2



20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL			C15458 C15460		
Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2
Pack containing 9 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C15458 C15460	See Schedule 2	See Schedule 2

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

*insert:*

Patisiran	Solution concentrate for I.V. infusion 10 mg in 5 mL	Injection	Onpattro	C15453 C15478 C15501	See Schedule 2	See Schedule 2
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**[11] Schedule 1, entry for Tadalafil [Brands: Adcirca; Tadalca; and TADALIS 20]**

- (a) omit from the column headed "Circumstances": **C13484**  
(b) omit from the column headed "Circumstances": **C13629**  
(c) insert in numerical order in the column headed "Circumstances": **C15508 C15515**

**[12] Schedule 1, after entry for Tadalafil [Brand: TADALIS 20]**

*insert:*

	Tadalafil 20	C15463 C15464 C15486 C15494 C15495 C15505 C15513 C15525		See Schedule 2	See Schedule 2
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**[13] Schedule 1, after entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg [Brand: Tenofovir APOTEX; Maximum quantity: 60; Maximum repeats: 2]**

*insert:*

	TENOFOVIR ARX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2
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**[14] Schedule 1, after entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg [Brand: Tenofovir APOTEX; Maximum quantity: 60; Maximum repeats: 5]**

*insert:*

	TENOFOVIR ARX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5
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**[15] Schedule 1, entry for Valganciclovir in the form Tablet 450 mg (as hydrochloride)**

*omit:*

	VALGANCICLOVIR HETERO	C4980 C4989 C9316		120	5
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**[16] Schedule 1, entry for Zoledronic acid [Maximum quantity: 1; Maximum repeats: 0]**

*insert as first entry:*

	DEZTRON	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735	P14729 P14735	1	0
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**[17] Schedule 1, entry for Zoledronic acid [Brand: DEZTRON; Maximum quantity: 1; Maximum repeats: 11]**

(a) *insert in numerical order in the column headed "Circumstances":* **C14729 C14735**

(b) *insert in numerical order in the column headed "Purposes":* **P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328**

**[18] Schedule 2, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor**

*insert in numerical order in the column headed "Circumstances":* **C15482 C15511**

**[19] Schedule 2, entry for Onasemnogene abeparvovec**

(a) *omit from the column headed "Circumstances":* **C14469**

(b) *insert in numerical order in the column headed "Circumstances":* **C15458 C15460**

**[20] Schedule 2, after entry for Pasireotide**

*insert:*

Patisiran	C15453 C15478 C15501	1 pack	7
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**[21] Schedule 2, entry for Tadalafil**

*substitute:*

Tadalafil	C11229 C13482 C13569 C13570 C13572 C13573 C15508 C15515	Sufficient for treatment for 1 month	5
	C15463 C15464 C15486 C15494 C15495 C15505 C15513 C15525	60 tablets	5

**[22] Schedule 3, entry for Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor**

*insert in numerical order after existing text:*

	C15482		Cystic fibrosis	Compliance with Written Authority Required
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		<p>Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.</p> <p>Patient must be 2 to 5 years of age.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	procedures
	C15511	<p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be 2 to 5 years of age.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include:</p> <p>(1) details of the proposed prescription; and</p>	Compliance with Written Authority Required procedures

			(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.	
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**[23] Schedule 3, entry for Onasemnogene abeparvovec**

**(a) omit:**

	C14469		<p>Spinal muscular atrophy (SMA) Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec) The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes. Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition; AND Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased. Patient must be no older than 9 months of age; AND Patient must have symptomatic Type 1 SMA; OR Patient must have pre-symptomatic SMA. 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). Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA. Confirm that a previous PBS authority application has been approved for one of the following: (i) Symptomatic Type 1 SMA; or (ii) Pre-symptomatic SMA. State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials. Adhere to any Product Information or local treatment guidelines with respect to treatment-free</p>	Compliance with Written Authority Required procedures
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			('wash out') periods prior to administering this benefit.	
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**(b)** insert in numerical order after existing text:

	C15458		<p>Spinal muscular atrophy (SMA)</p> <p>Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen to onasemnogene abeparvovec)</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.</p> <p>Patient must be no older than 9 months of age; AND</p> <p>Patient must have pre-symptomatic SMA with 3 copies of the SMN2 gene.</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>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.</p> <p>Confirm that a previous PBS authority application has been approved for pre-symptomatic SMA with 3 copies of SMN2 gene.</p> <p>State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.</p> <p>Adhere to any Product Information or local treatment guidelines with respect to treatment-free</p>	Compliance with Written Authority Required procedures
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			('wash out') periods prior to administering this benefit.	
	C15460		<p>Spinal muscular atrophy (SMA)</p> <p>Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.</p> <p>Patient must be no older than 9 months of age; AND</p> <p>Patient must have symptomatic Type 1 SMA; OR</p> <p>Patient must have pre-symptomatic SMA with 1-2 copies of SMN2 gene.</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>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.</p> <p>Confirm that a previous PBS authority application has been approved for one of the following:</p> <p>(i) Symptomatic Type 1 SMA; or</p> <p>(ii) Pre-symptomatic SMA with 1-2 copies of SMN2 gene.</p> <p>State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.</p> <p>Adhere to any Product Information or local treatment guidelines with respect to treatment-free</p>	Compliance with Written Authority Required procedures

			('wash out') periods prior to administering this benefit.	
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**[24] Schedule 3, after entry for Pasireotide**

*insert:*

Patisiran	C15453		<p>Hereditary transthyretin amyloidosis</p> <p>Initial treatment</p> <p>Patient must have either: (i) stage 1 polyneuropathy, (ii) stage 2 polyneuropathy.</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.</p> <p>Patient must be at least 18 years of age.</p> <p>The condition must be hereditary transthyretin amyloidosis confirmed by genetic testing; AND</p> <p>Patient must have a Polyneuropathy Disability (PND) score description of either I, II, IIIA, IIIB; OR</p> <p>Patient must have a Familial Amyloid Polyneuropathy (FAP) stage description of 1 or 2; AND</p> <p>Patient must not have previously undergone a liver transplant; AND</p> <p>Patient must not exhibit heart failure symptoms (defined as New York Heart Association NYHA class III or IV).</p> <p>Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders; AND</p> <p>Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders).</p> <p>PND scores in the context of this PBS restriction are:</p> <p>Stage 0 - No symptoms;</p> <p>Stage I - Sensory disturbances but preserved walking capability;</p> <p>Stage II - Impaired walking capacity but able to walk without stick or crutches;</p> <p>Stage IIIA - Walking with help of one stick or crutch;</p> <p>Stage IIIB - Walking with help of two sticks or crutches;</p> <p>Stage IV - Confined to wheelchair or bedridden.</p> <p>FAP stage in the context of this PBS restriction are:</p> <p>Stage 0 - No symptoms;</p> <p>Stage 1 - Unimpaired ambulation;</p> <p>Stage 2 - Assistance with ambulation required;</p> <p>Stage 3 - Wheelchair-bound or bedridden.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p>	Compliance with Written Authority Required procedures
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			<p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) details of the proposed prescription; 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>	
	C15478		<p>Hereditary transthyretin amyloidosis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received treatment with this drug for this condition prior to 1 August 2024; AND</p> <p>Patient must continue to demonstrate clinical benefit; AND</p> <p>Patient must not be permanently bedridden; OR</p> <p>Patient must not be receiving end-of-life care.</p> <p>Applications for authorisation under this treatment phase 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) details of the proposed prescription; 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 Written Authority Required procedures
	C15501		<p>Hereditary transthyretin amyloidosis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must continue to demonstrate clinical benefit; AND</p> <p>Patient must not be permanently bedridden; OR</p> <p>Patient must not be receiving end-of-life care.</p> <p>Applications for authorisation under this treatment phase 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) details of the proposed prescription; 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 Written Authority Required procedures

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

**(a) omit:**

	C13484		Pulmonary arterial hypertension (PAH)	Compliance with Written
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		<p>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:  - 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>	<p>Authority Required procedures</p>
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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.  The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.  A maximum of 5 repeats may be requested.</p>	
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**(b) omit:**

	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  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 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 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;</p>	<p>Compliance with Written Authority Required procedures</p>
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			<p>- 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 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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**(c)** *insert in numerical order after existing text:*

	C15463		<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.  Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	Compliance with Authority Required procedures
	C15464		<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;</p>	Compliance with Written Authority Required procedures

		<p>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) details of the proposed prescription; 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"> <li>- RHC composite assessment; and</li> <li>- ECHO composite assessment; and</li> <li>- 6 Minute Walk Test (6MWT)</li> </ul> <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"> <li>- RHC plus ECHO composite assessments;</li> <li>- RHC composite assessment plus 6MWT;</li> <li>- RHC composite assessment only.</li> </ul> <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"> <li>- ECHO composite assessment plus 6MWT;</li> <li>- ECHO composite assessment only.</li> </ul> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant</p>	
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		<p>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> <p>Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	
	C15486	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (new patients)</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>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) details of the proposed prescription; 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> <p>- RHC composite assessment; and</p>	Compliance with Written Authority Required procedures

		<p>- 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:</p> <p>- 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:</p> <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:</p> <p>(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 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.</p> <p>A maximum of 5 repeats may be requested.</p> <p>Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	
	C15494	<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  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)</p>	Compliance with Authority Required procedures

		<p>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> <p>Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	
	C15495	<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> <p>Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	Compliance with Authority Required procedures
	C15505	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition</p>	Compliance with Authority Required procedures



		<p>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> <p>Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	
	C15508	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (new patients)</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>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) details of the proposed prescription; and</p>	Compliance with Written Authority Required procedures

		<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"> <li>- RHC composite assessment; and</li> <li>- ECHO composite assessment; and</li> <li>- 6 Minute Walk Test (6MWT)</li> </ul> <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"> <li>- RHC plus ECHO composite assessments;</li> <li>- RHC composite assessment plus 6MWT;</li> <li>- RHC composite assessment only.</li> </ul> <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"> <li>- ECHO composite assessment plus 6MWT;</li> <li>- ECHO composite assessment only.</li> </ul> <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.</p> <p>A maximum of 5 repeats may be requested.</p>	
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	C15513		<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> <p>Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	Compliance with Authority Required procedures
	C15515		<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) details of the proposed prescription; 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 Written Authority Required procedures

		<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"> <li>- RHC composite assessment; and</li> <li>- ECHO composite assessment; and</li> <li>- 6 Minute Walk Test (6MWT)</li> </ul> <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"> <li>- RHC plus ECHO composite assessments;</li> <li>- RHC composite assessment plus 6MWT;</li> <li>- RHC composite assessment only.</li> </ul> <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"> <li>- ECHO composite assessment plus 6MWT;</li> <li>- ECHO composite assessment only.</li> </ul> <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>	
	C15525	<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</p>	Compliance with Authority Required procedures

		<p>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> <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.</p> <p>A maximum of 5 repeats may be requested.</p> <p>Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.</p>	
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