



**PB 55 of 2024**

# **National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (June 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 May 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 (June Update) Instrument 2024*.
- (2) This instrument may also be cited as PB 55 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 June 2024</i>	<i>1 June 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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) avatrombopag;
- (e) azacitidine;
- (f) benralizumab;
- (g) bosentan;
- (h) burosumab;
- (i) difelikefalin;
- (j) dupilumab;
- (k) eculizumab;
- (l) elexacaftor with tezacaftor and with ivacaftor, and ivacaftor;
- (m) eltrombopag;
- (n) epoprostenol;
- (o) etanercept;
- (p) iloprost;
- (q) infliximab;
- (r) ivacaftor;
- (s) lenalidomide;
- (t) lumacaftor with ivacaftor;

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

**[2] Schedule 1, entry for Ambrisentan in the form Tablet 5 mg**

*omit:*

	Ambrisentan Mylan	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582	See Schedule 2	See Schedule 2
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**[3] Schedule 1, entry for Azacitidine**

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

	AZACITIDINE EUGIA	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029	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)**

*omit:*

	Tracleer	C11229 C12425 C13495 C13496 C13497 C13499 C13571 C13582 C13632	See Schedule 2	See Schedule 2
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**[5] Schedule 1, entry for Bosentan in the form Tablet 125 mg (as monohydrate)**

*omit:*

	Tracleer	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632	See Schedule 2	See Schedule 2
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**[6] Schedule 1, entry for Ciclosporin in the form Capsule 10 mg**

**(a)** *omit from the column headed "Circumstances":* **C13122 C13168**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C15259 C15300**

**[7] Schedule 1, entry for Ciclosporin in each of the forms: Capsule 25 mg; Capsule 50 mg; and Capsule 100 mg**

**(a)** *omit from the column headed "Circumstances" (all instances):* **C13122 C13168**

**(b)** *insert in numerical order in the column headed "Circumstances" (all instances):* **C15259 C15300**

**[8] Schedule 1, entry for Ciclosporin in the form Oral liquid 100 mg per mL, 50 mL**

**(a)** *omit from the column headed "Circumstances":* **C13122 C13168**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C15259 C15300**

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**[9] Schedule 1, entry for Ivacaftor**

*substitute:*

Ivacaftor	Sachet containing granules 25 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255	See Schedule 2	See Schedule 2
	Sachet containing granules 50 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255	See Schedule 2	See Schedule 2
	Sachet containing granules 75 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255	See Schedule 2	See Schedule 2
	Tablet 150 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255	See Schedule 2	See Schedule 2

**[10] Schedule 1, entry for Lamivudine with Zidovudine**

*omit:*

			Lamivudine 150 mg + Zidovudine 300 mg Alphapharm	C4454 C4512	120	5
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**[11] Schedule 1, entry for Mepolizumab in the form Injection 100 mg in 1 mL single dose pre-filled pen**

*omit from the column headed "Circumstances": C13864*

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

*omit:*

			Noumed Mycophenolate	C5554 C5795 C9691 C9693	300	5
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**[13] Schedule 1, entry for Plerixafor**

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

			PLERIXAFOR EUGIA	C4549 C9329	1	1
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**[14] Schedule 1, entry for Raltegravir**

*omit:*

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Tablet 25 mg (as potassium)	Oral	Isentress	C4274 C4275	360	5
Tablet 100 mg (as potassium)	Oral	Isentress	C4274 C4275	360	5

**[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**

**(c) omit from the column headed "Circumstances": C6645 C6664 C7629**

**(d) insert in numerical order in the column headed "Circumstances": C15271 C15272 C15274**

**[16] Schedule 1, entry for Ruxolitinib in the form Tablet 5 mg [Maximum Quantity: 56; Number of Repeats: 0]**

*omit from the column headed "Circumstances": C13877 C13891*

**[17] Schedule 1, entry for Ruxolitinib in the form Tablet 5 mg [Maximum Quantity: 56; Number of Repeats: 5]**

**(a) omit from the column headed "Circumstances": C13877 C13891**

**(b) omit from the column headed "Purposes": P13877 P13891**

**[18] Schedule 1, entry for Ruxolitinib in the form Tablet 10 mg [Maximum Quantity: 56; Number of Repeats: 0]**

*omit from the column headed "Circumstances": C13877 C13891*

**[19] Schedule 1, entry for Ruxolitinib in the form Tablet 10 mg [Maximum Quantity: 56; Number of Repeats: 5]**

**(a) omit from the column headed "Circumstances": C13877 C13891**

**(b) omit from the column headed "Purposes": P13877 P13891**

**[20] Schedule 1, entry for Selinexor**

*substitute:*

Selinexor	Tablet 20 mg	Oral	Xpovio	C14021 C14022	P14021 P14022	16	2
				C14023 C14024	P14045		
				C14031 C14037			
				C14039 C14045			
				C14021 C14022	P14023 P14024	20	2
				C14023 C14024	P14037		
				C14031 C14037			
				C14039 C14045			
				C14021 C14022	P14031 P14039	32	2



C14023 C14024  
C14031 C14037  
C14039 C14045

**[21] Schedule 2, entry for Ivacaftor**

*omit from the column headed "Circumstances":* **C12624 C12625** *substitute:* **C15251 C15252 C15253 C15255**

**[22] Schedule 2, entry for Mepolizumab [Maximum Quantity: 1; Maximum Repeats: 5]**

*omit from the column headed "Circumstances":* **C13864**

**[23] Schedule 2, entry for Riociguat [Maximum Quantity: Sufficient for treatment for 1 month; Maximum Repeats: 3]**

*omit from the column headed "Circumstances":* **C6664** *substitute:* **C15274**

**[24] Schedule 2, entry for Riociguat [Maximum Quantity: Sufficient for treatment for 1 month; Maximum Repeats: 5]**

**(a)** *omit from the column headed "Circumstances":* **C6645 C7629**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C15271 C15272**

**[25] Schedule 2, omit entry for Selinexor**

**[26] Schedule 3, entry for Ciclosporin**

**(a)** *omit:*

	C13122	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 13122
	C13168	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 13168

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

	C15259	<p>Severe psoriasis  Management (initiation, stabilisation and review of therapy)  The condition must be ineffective to other systemic therapies; OR  The condition must be inappropriate for other systemic therapies; AND  The condition must have caused significant interference with quality of life.  Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR  Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.  For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.  This assessment must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15259
	C15300	<p>Severe psoriasis  Management (initiation, stabilisation and review of therapy)  The condition must be ineffective to other systemic therapies; OR  The condition must be inappropriate for other systemic therapies; AND  The condition must have caused significant interference with quality of life.  Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR  Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.  For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.  This assessment must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15300

**[27] Schedule 3, entry for Infliximab**

**(a)** *omit entry for Circumstances Code "C13692" and substitute:*

	C13692	<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 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 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 recommence 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. 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 Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration 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. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last</p>	Compliance with Written Authority Required procedures
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			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.	
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**(b)** omit entry for Circumstances Code “C13719” and substitute:

	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 recommence 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. 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. 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
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			<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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**[28] Schedule 3, entry for Ivacaftor**

*substitute:*

Ivacaftor	C15251		<p>Cystic fibrosis</p> <p>Initial treatment - New patient (gating mutations)</p> <p>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR</p> <p>Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 4 months or older.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.</p>	Compliance with Written Authority Required procedures
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		<p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (i) the specific CFTR mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) 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>	
	C15252	<p>Cystic fibrosis</p> <p>Continuing treatment (gating mutations)</p> <p>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction per authority application; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 4 months or older.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate</p>	Compliance with Written Authority Required procedures

		<p>CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.</p> <p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C15253	<p>Cystic fibrosis</p> <p>Initial treatment - New patient (non-gating mutations)</p> <p>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data; AND</p> <p>Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 4 months or older.</p> <p>For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate</p>	Compliance with Written Authority Required procedures

		<p>CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.  Ivacaftor is not PBS-subsidised for this condition as a sole therapy.  Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:  Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort  Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin  Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.  The authority application must be in writing and must include:  (1) a completed authority prescription; and  (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and  (3) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA approved Product Information. Quote each of the: (i) the specific mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and  (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C15255	<p>Cystic fibrosis  Continuing treatment (non-gating mutations)  Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND  Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND  Patient must not receive more than 24 weeks of treatment under this restriction per authority application; AND  The treatment must be given concomitantly with standard therapy for this condition.  Patient must be aged 4 months or older.  Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.  Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors:</p>	Compliance with Written Authority Required procedures



			<p>amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.</p> <p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
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**[29] Schedule 3, entry for Mepolizumab**

*omit:*

	C13864		<p>Chronic rhinosinusitis with nasal polyps (CRSwNP)</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND</p> <p>Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are described below.</p> <p>Patient must be at least 18 years of age.</p> <p>Criteria for Grandfathered patients are that:</p> <p>(a) the diagnosis of CRSwNP was confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan; or from at least two physicians of the above mentioned prescriber types</p> <p>(b) the patient has undergone surgery for the removal of nasal polyps; or the patient has the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery</p> <p>(c) the patient had, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10)</p> <p>(d) the treatment was/is not used in combination with and within 4 weeks of another</p>	Compliance with Written Authority Required procedures
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			<p>PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma</p> <p>(e) the patient had failed to achieve adequate control with optimised nasal polyp therapy which has been documented</p> <p>(f) the patient had a blood eosinophil count greater than or equal to 300 cells per microlitre in the 12 months preceding treatment.</p> <p>Optimised nasal polyp therapy includes:</p> <p>(a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated</p> <p>(b) if required, nasal irrigation with saline</p> <p>Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form,</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>(c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,</p> <p>(d) details (date and treatment) of nasal polyp surgery; or</p> <p>(e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,</p> <p>(f) the eosinophil count and date,</p> <p>(g) two of the following, measured within the 12 months prior to non-PBS-subsidised treatment: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.</p>	
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**[30] Schedule 3, entry for Nusinersen**

**(a)** omit entry for Circumstances Code "C14370" and substitute:

	C14370		<p>Spinal muscular atrophy (SMA)</p> <p>Changing the prescribed therapy</p> <p>Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Patient must be untreated with gene therapy; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a</p>	Compliance with Authority Required procedures
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			<p>potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.</p>	
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**(b)** omit entry for Circumstances Code “C14421” and substitute:

	C14421		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)</p> <p>Changing the prescribed therapy</p> <p>Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Patient must be untreated with gene therapy; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.</p>	Compliance with Authority Required procedures
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**(c)** omit entry for Circumstances Code “C15069” and substitute:

	C15069		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing</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; or initiated 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; AND</p>	Compliance with Authority Required procedures
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			<p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.</p>	
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**(d)** omit entry for Circumstances Code "C15112" and substitute:

	C15112		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing</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; or initiated 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; AND</p> <p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the</p>	Compliance with Authority Required procedures
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			<p>absence of a potentially reversible cause while being treated with this drug.</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.</p>	
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**[31] Schedule 3, entry for Raltegravir**

*omit:*

	C4274		<p>HIV infection Continuing</p> <p>The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have previously received PBS-subsidised therapy for HIV infection. Patient must be aged 2 years or older.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4274
	C4275		<p>HIV infection Initial</p> <p>The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease. Patient must be aged 2 years or older.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4275

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

**(a)** *omit:*

	C6645		<p>Chronic thromboembolic pulmonary hypertension (CTEPH) Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must demonstrate stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be aged 18 years or older. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC</p>	Compliance with Written Authority Required procedures
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		<p>composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).</p> <p>Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:</p> <ol style="list-style-type: none"> <li>(1) RHC plus ECHO composite assessments plus 6MWT;</li> <li>(2) RHC plus ECHO composite assessments;</li> <li>(3) RHC composite assessment plus 6MWT;</li> <li>(4) ECHO composite assessment plus 6MWT;</li> <li>(5) RHC composite assessment only;</li> <li>(6) ECHO composite assessment only.</li> </ol> <p>The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.</p> <p>The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.</p> <p>Response to this drug is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.</p> <p>The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.</p> <p>A maximum of 5 repeats will be authorised.</p> <p>Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.</p> <p>Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
	C6664	<p>Chronic thromboembolic pulmonary hypertension (CTEPH) Initial treatment Patient must have WHO Functional Class II, III or IV CTEPH; AND</p>	<p>Compliance with Written Authority Required procedures</p>

		<p>The condition must be inoperable by pulmonary endarterectomy; OR  The condition must be recurrent or persistent following pulmonary endarterectomy; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Must be treated in a centre with expertise in the management of CTEPH.  Patient must be aged 18 years or older.  CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:  Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm-5 measured at least 90 days after start of full anticoagulation; and  A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.  CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:  RHC demonstrating a PVR of greater than 300 dyn*sec*cm-5 measured at least 180 days following pulmonary endarterectomy.  Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.  Applications for authorisation must be in writing and must include:(1) completed authority prescription forms sufficient for dose titration; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.  Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(3) RHC composite assessment only.  In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.  Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.  The test results provided must not be more than 2 months old at the time of application.  Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information.  No repeats will be authorised for these prescriptions.  Approvals for subsequent authority prescription will be limited to 1 month of treatment, the quantity approved must be based on the dosage recommendations in the TGA-approved Product</p>	
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			<p>Information, and a maximum of 3 repeats.</p> <p>The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
	C7629		<p>Chronic thromboembolic pulmonary hypertension (CTEPH)</p> <p>Balance of supply</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction; AND</p> <p>The treatment must be the sole PBS-subsidised agent for this condition.</p> <p>Must be treated in a centre with expertise in the management of CTEPH.</p> <p>Patient must be aged 18 years or older.</p>	Compliance with Authority Required procedures

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

	C15271		<p>Chronic thromboembolic pulmonary hypertension (CTEPH)</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 demonstrate stable or responding disease; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Must be treated in a centre with expertise in the management of CTEPH.</p> <p>Patient must be at least 18 years of age.</p> <p>Response to this drug is defined as follows:</p> <p>For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.</p> <p>For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.</p> <p>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.</p> <p>Test requirements to establish response to treatment for continuation of treatment are as follows:</p> <p>The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:</p>	Compliance with Authority Required procedures
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		<p>(1) RHC plus ECHO composite assessments plus 6MWT;  (2) RHC plus ECHO composite assessments;  (3) RHC composite assessment plus 6MWT;  (4) ECHO composite assessment plus 6MWT;  (5) RHC composite assessment only;  (6) ECHO composite assessment only.</p> <p>The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records.</p> <p>The test results conducted for continuing treatment must be no more than 2 months old at the time of application.</p> <p>The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.</p> <p>A maximum of 5 repeats will be authorised.</p> <p>Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
	C15272	<p>Chronic thromboembolic pulmonary hypertension (CTEPH)</p> <p>Balance of supply</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Must be treated in a centre with expertise in the management of CTEPH.</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures

	C15274	<p>Chronic thromboembolic pulmonary hypertension (CTEPH) Initial treatment Patient must have WHO Functional Class II, III or IV CTEPH; AND The condition must be inoperable by pulmonary endarterectomy; OR The condition must be recurrent or persistent following pulmonary endarterectomy; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be at least 18 years of age. CTEPH that is inoperable by pulmonary endarterectomy is defined as follows: (a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm-5 measured at least 90 days after start of full anticoagulation; and (b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation. CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows: RHC demonstrating a PVR of greater than 300 dyn*sec*cm-5 measured at least 180 days following pulmonary endarterectomy. Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be documented in the patient's medical records. 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). The following must be provided at the time of application and documented in the patient's medical records: (a) the results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or</p>	Compliance with Written Authority Required procedures
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			<p>(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.</p> <p>Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:</p> <p>(1) RHC plus ECHO composite assessments;</p> <p>(2) RHC composite assessment plus 6MWT;</p> <p>(3) RHC composite assessment only.</p> <p>In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.</p> <p>The test results provided must not be more than 2 months old at the time of application.</p> <p>Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment. The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.</p> <p>The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
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**[33] Schedule 3, entry for Risdiplam**

*omit entry for Circumstances Code "C15095" and substitute:*

	C15095		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND</p>	Compliance with Authority Required procedures
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			<p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND</p> <p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age: 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p>	
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**[34] Schedule 3, entry for Ruxolitinib**

*omit:*

	C13877	P13877	<p>Grade II to IV acute graft versus host disease (aGVHD)</p> <p>Grandfather treatment (transition from non-PBS-subsidised treatment)</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13877</p>
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			<p>Patient must have received systemic steroid treatment prior to initiation of this drug for this condition; AND</p> <p>Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND</p> <p>Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR</p> <p>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.</p> <p>Steroid-refractory disease is defined as:</p> <p>(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or</p> <p>(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.</p> <p>Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:</p> <p>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or</p> <p>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.</p> <p>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.</p> <p>Details of prior steroid use should be documented in the patient's medical records.</p> <p>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.</p> <p>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
	C13891	P13891	Grade II to IV acute graft versus host disease (aGVHD)	Compliance with Authority

		<p>Grandfather treatment (transition from non-PBS-subsidised treatment)  Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND  Patient must have received systemic steroid treatment prior to initiation of this drug for this condition; AND  Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND  Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.  Must be treated by a haematologist; OR  Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.  Steroid-refractory disease is defined as:  (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or  (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.  Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:  (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or  (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.  Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.  Details of prior steroid use should be documented in the patient's medical records.  Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.  (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.  (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.  The assessment of response must be documented in the patient's medical records.  Tapering the dose of corticosteroids should be considered in patients with responding disease.  Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p>	<p>Required procedures -  Streamlined Authority Code  13891</p>
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			This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
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**[35] Schedule 3, entry for Selinexor**

- (a) for the entry for Circumstances Code “C14021”, insert in the column headed “Purposes Code”: **P14021**
- (b) for the entry for Circumstances Code “C14022”, insert in the column headed “Purposes Code”: **P14022**
- (c) for the entry for Circumstances Code “C14023”, insert in the column headed “Purposes Code”: **P14023**
- (d) for the entry for Circumstances Code “C14024”, insert in the column headed “Purposes Code”: **P14024**
- (e) for the entry for Circumstances Code “C14031”, insert in the column headed “Purposes Code”: **P14031**
- (f) for the entry for Circumstances Code “C14037”, insert in the column headed “Purposes Code”: **P14037**
- (g) for the entry for Circumstances Code “C14039”, insert in the column headed “Purposes Code”: **P14039**
- (h) for the entry for Circumstances Code “C14045”, insert in the column headed “Purposes Code”: **P14045**

**[36] Schedule 3, entry for Sildenafil [Circumstances Code: C13629]**

omit from the column headed “Authority Requirements-Part of Circumstances”: **Compliance with Authority Required procedures**  
 substitute: **Compliance with Written Authority Required procedures**

**[37] Schedule 3, entry for Tadalafil [Circumstances Code: C13629]**

omit from the column headed “Authority Requirements-Part of Circumstances”: **Compliance with Authority Required procedures**  
 substitute: **Compliance with Written Authority Required procedures**