Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

August 2023

PHARMAC
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Contents

Summary of decisions
EFFECTIVE 1 AUGUST 2023

- Ambrisentan tab 5 mg (Ambrisentan Mylan and Ambrisentan Viatris) and tab 10 mg (Mylan and Ambrisentan Viatris) – amended restriction criteria
- Atezolizumab (Tecentriq) inj 60 mg per ml, 2 ml vial – amended restriction criteria
- Bosentan (Bosentan Dr Reddy's) tab 62.5 mg and 125 mg – amended restriction criteria
- Capecitabine (Capecitabine Viatris) tab 150 mg and 500 mg – new listing and addition of PSS
- Capecitabine (Capercit) tab 150 mg and 500 mg – to be delisted 1 January 2024
- Chlorpromazine hydrochloride (Largactil) tab 10 mg – to be delisted 1 April 2024
- Daptomycin (Cubicin) inj 500 mg vial – to be delisted 1 January 2024
- Daptomycin (Daptomycin Dr Reddy's) inj 500 mg vial – new listing and addition of PSS
- Enalapril maleate (Acetec) tab 5 mg, 10 mg and 20 mg, 90 tab pack – amendment of PSS
- Enalapril maleate (Acetec) tab 5 mg, 10 mg and 20 mg, 100 tab pack – to be delisted 1 February 2024
- Epoprostenol (Veletri) inj 500 mcg vial and 1.5 mg vial – amended restriction criteria
- Fluconazole (Diflucan) oral liquid 50 mg per 5 ml – price increase
- Gentamicin sulphate eye drops 0.3% – new listing
- Hydrocortisone (Noumed) crm 1 %, 500 g – addition of note
- Iloprost (Vebulis) nebuliser soln 10 mcg per ml, 2 ml – amended restriction criteria
- Indometacin [Indomethacin] cap 25 mg and 50 mg, cap long-acting 75 mg, inj 1 mg vial and suppos 100 mg – amended chemical name
- Metformin hydrochloride (Metformin Mylan) tab immediate-release 850 mg – removal of PSS and delisting
- Metformin hydrochloride (Metformin Viatris) tab immediate-release 850 mg – addition of PSS
- Montelukast (Montelukast Viatris) tab 4 mg – new listing
- Naproxen (Noflam 250) tab 250 mg – new Pharmacode listing
- Nifedipine (Tensipine MR10) tab long-acting 10 mg – removal of restriction
- Pembrolizumab (Keytruda) inj 25 mg per ml, 4 ml vial – amended restriction criteria

Summary of decisions – effective 1 August 2023 (continued)

- Pilocarpine nitrate eye drops 2%, single dose – amended chemical name
- Sildenafil (Vedafil) tab 25 mg, 50 mg and 100 mg – amended restriction criteria
- Tramadol hydrochloride (Arrow-Tramadol) cap 50 mg – price increase and addition of PSS
- Venetoclax (Venclexta) tab 10 mg, 14 tab pack – to be delisted 1 December 2023
- Venetoclax (Venclexta) tab 10 mg, 2 tab pack – new listing

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Section H changes to Part II

Effective 1 August 2023

ALIMENTARY TRACT AND METABOLISM

11 METFORMIN HYDROCHLORIDE (removal of PSS and delisting)
Tab immediate-release 850 mg
– 1% DV Mar-22 to ~~2024~~ **31/07/2023**..... **1**1.28 500 Metformin Mylan
Note – Metformin Mylan tab immediate-release 850 mg to be delisted from 1 January 2024.

11 METFORMIN HYDROCHLORIDE (addition of PSS)
Tab immediate-release 850 mg
– **1% DV Aug-23 to 2024**..... 11.28 500 **Metformin Viatris**

CARDIOVASCULAR SYSTEM

44 ENALAPRIL MALEATE (amendment of PSS)
Tab 5 mg – **5% DV Feb-24** ~~Sep-23~~ **to 2025**..... 1.75 90 **Acetec**
Tab 10 mg – **5% DV Feb-24** ~~Sep-23~~ **to 2025**..... 1.97 90 **Acetec**
Tab 20 mg – **5% DV Feb-24** ~~Sep-23~~ **to 2025**..... 2.35 90 **Acetec**
Note: Acetec tab 5 mg, 10 mg and 20 mg, 100 tab pack to be delisted from 1 February 2024.

49 NIFEDIPINE (removal of restriction)
➔Tab long-acting 10 mg
~~– Restricted: For continuation only~~..... 18.80 56 Tensipine MR10

56 AMBRISENTAN (amended restriction criteria)
➔Tab 5 mg – **5% DV Dec-23 to 2026**..... 1,550.00 30 Ambrisentan Mylan
200.00 **Ambrisentan Viatris**
➔Tab 10 mg – **5% DV Dec-23 to 2026**..... 200.00 30 **Ambrisentan Viatris**
1,550.00 Mylan

Restricted
~~Initiation~~
~~Either:~~
~~1 For use in patients with a valid Special Authority approval for ambrisentan by the Pulmonary Arterial Hypertension Panel; or~~
~~2 In-hospital stabilisations in emergency situations.~~

Initiation – Pulmonary arterial hypertension
Respiratory specialist or cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist.
Re-assessment required after 6 months
All of the following:
1 Patient has pulmonary arterial hypertension (PAH); and
2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
4 Any of the following:
4.1 All of the following:
4.1.1 PAH has been confirmed by right heart catheterisation; and
4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm-5); and
4.1.5 Any of the following:
4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines)†; or
4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool; or**
4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
5 Any of the following:
5.1 Both:
5.1.1 Ambrisentan is to be used as PAH monotherapy; and
5.1.2 Any of the following:
5.1.2.1 Patient has experienced intolerable side effects with both sildenafil and bosentan; or
5.1.2.2 Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
5.1.2.3 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease; or
5.2 All of the following:
5.2.1 Ambrisentan is to be used as PAH dual therapy; and
5.2.2 Either:
5.2.2.1 Patient has tried a PAH monotherapy (sildenafil or bosentan) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool; or**
5.2.2.2 Patient has tried PAH dual therapy including bosentan and has experienced intolerable side effects on bosentan; and
5.2.3 Both:
5.2.3.1 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would benefit from initial dual therapy; and
5.2.3.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
5.3 Both:
5.3.1 Ambrisentan is to be used as PAH triple therapy; and
5.3.2 Any of the following:
5.3.2.1 Patient is on the lung transplant list; or
5.3.2.2 Both:
5.3.2.2.1 Patient is presenting in NYHA/WHO functional class IV; and
5.3.2.2.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
5.3.2.3 Both:
5.3.2.3.1 Patient has tried PAH dual therapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool; and**
5.3.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

Continuation - Pulmonary arterial hypertension
Respiratory specialist, cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist.
Approvals valid for 2 years where the patient is continuing to derive benefit from ambrisentan treatment according to a validated PAH risk stratification tool.**
Note
† The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension
**** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.**

56 BOSENTAN (amended restriction criteria)

➔ Tab 62.5 mg – **5% DV Dec-21 to 2024**	119.85	60	**Bosentan Dr Reddy's**
➔ Tab 125 mg – **5% DV Dec-21 to 2024**	119.85	60	**Bosentan Dr Reddy's**

~~Restricted~~
~~Initiation – Pulmonary arterial hypertension~~
~~*Re-assessment required after 6 months*~~
~~Either:~~
~~1. All of the following:~~
~~1.1. Patient has pulmonary arterial hypertension (PAH); and~~
~~1.2. PAH is in Group 1, 4 or 5 of the WHO (Venice) clinical classifications; and~~
~~1.3. PAH is at NYHA/WHO functional class II, III, or IV; and~~
~~1.4. Any of the following:~~
~~1.4.1. Both:~~
~~1.4.1.1. Bosentan is to be used as PAH monotherapy; and~~
~~1.4.1.2. Either:~~
~~1.4.1.2.1. Patient is intolerant or contraindicated to sildenafil; or~~
~~1.4.1.2.2. Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease; or~~
~~1.4.2. Both:~~
~~1.4.2.1. Bosentan is to be used as PAH dual therapy; and~~
~~1.4.2.2. Either:~~
~~1.4.2.2.1. Patient has tried a PAH monotherapy for at least three months and failed to respond; or~~
~~1.4.2.2.2. Patient deteriorated while on a PAH monotherapy; or~~
~~1.4.3. Both:~~
~~1.4.3.1. Bosentan is to be used as PAH triple therapy; and~~
~~1.4.3.2. Any of the following:~~
~~1.4.3.2.1. Patient is on the lung transplant list; or~~
~~1.4.3.2.2. Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or 1.4.3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or~~
~~1.4.3.2.4. Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy; or~~
~~2. In-hospital stabilisation in emergency situations.~~

~~Continuation – Pulmonary arterial hypertension *Re-assessment required after 6 months*~~
~~Any of the following:~~

continued...

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

~~1 Both:~~
~~1.1 Bosentan is to be used as PAH monotherapy; and~~
~~1.2 Patient is stable or has improved while on bosentan; or~~
~~2 Both:~~
~~2.1 Bosentan is to be used as PAH dual therapy; and~~
~~2.2 Patient has tried a PAH monotherapy for at least three months and either failed to respond or later deteriorated; or~~
~~3 Both:~~
~~3.1 Bosentan is to be used as PAH triple therapy; and~~
~~3.2 Any of the following:~~
~~3.2.1 Patient is on the lung transplant list; or~~
~~3.2.2 Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or~~
~~3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or~~
~~3.2.4 Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy.~~

Restricted
Initiation
Respiratory specialist or cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist.
Re-assessment required after 6 months
All of the following:
1 Patient has pulmonary arterial hypertension (PAH)*; and
2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
4 Any of the following:
4.1. All of the following:
4.1.1. PAH has been confirmed by right heart catheterisation; and
4.1.2. A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
4.1.3. A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
4.1.4. Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm-5); and
4.1.5. Any of the following:
4.1.5.1. PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines)†; or
4.1.5.2. Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool; or**
4.1.5.3. Patient has PAH other than idiopathic / heritable or drug-associated type; or
4.2. Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
4.3. Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
5 Any of the following:
5.1. Both:
5.1.1. Bosentan is to be used as PAH monotherapy; and
5.1.2. Any of the following:

continued...

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

5.1.2.1. Patient has experienced intolerable side effects on sildenafil; or
5.1.2.2. Patient has an absolute contraindication to sildenafil; or
5.1.2.3. Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease; or

5.2. Both:
5.2.1. Bosentan is to be used as part of PAH dual therapy; and
5.2.2. Either:
5.2.2.1. Patient has tried a PAH monotherapy (sildenafil) for at least three months and has experienced an inadequate therapeutic response to treatment according to a validated risk stratification tool; or**
5.2.2.2. Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would likely benefit from initial dual therapy; or

5.3. Both:
5.3.1. Bosentan is to be used as part of PAH triple therapy; and
5.3.2. Any of the following:
5.3.2.1. Patient is on the lung transplant list; or
5.3.2.2. Patient is presenting in NYHA/WHO functional class IV; or
5.3.2.3. Both:
5.3.2.3.1. Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool; and**
5.3.2.3.2. Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

Continuation
Respiratory specialist, cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years where patient is continuing to derive benefit from bosentan treatment according to a validated PAH risk stratification tool.**
Note
† The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension
**** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.**

57 SILDENAFIL (amended restriction criteria – new criteria shown only)

➔ Tab 25 mg – **5% DV Jan-22 to 2024**	0.85	4	**Vedafil**
➔ Tab 50 mg – **5% DV Jan-22 to 2024**	1.70	4	**Vedafil**
➔ Tab 100 mg – **5% DV Jan-22 to 2024**	10.20	12	**Vedafil**

~~Restricted~~
~~Initiation – tablets Pulmonary arterial hypertension~~
~~1. All of the following:~~
~~1.1. Patient has pulmonary arterial hypertension (PAH); and~~
~~1.2. Any of the following:~~
~~1.2.1. PAH is in Group 1 of the WHO (Venice) clinical classifications; or~~
~~1.2.2. PAH is in Group 4 of the WHO (Venice) clinical classifications; or~~
~~1.2.3. PAH is in Group 5 of the WHO (Venice) clinical classifications; and~~
~~1.3. Any of the following:~~
~~1.3.1. PAH is in NYHA/WHO functional class II; or~~
~~1.3.2. PAH is in NYHA/WHO functional class III; or~~
~~1.3.3. PAH is in NYHA/WHO functional class IV; and~~
~~1.4. Either:~~

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

~~1.4.1 All of the following:~~
~~1.4.1.1 Patient has a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and~~
~~1.4.1.2 Either:~~
~~1.4.1.2.1 Patient has a mean pulmonary artery pressure (PAPm) greater than 25 mmHg; or~~
~~1.4.1.2.2 Patient is peri Fontan repair; and~~
~~1.4.1.3 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dyn s cm-5); or~~
~~1.4.2 Testing for PCWP, PAPm, or PVR cannot be performed due to the patient's young age; or~~
~~2 For use in neonatal units for persistent pulmonary hypertension of the newborn (PPHN); or~~
~~3 In-hospital stabilisation in emergency situations.~~

Restricted
Initiation – tablets Pulmonary arterial hypertension
Respiratory specialist or cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist.
All of the following:
1 Patient has pulmonary arterial hypertension (PAH)*; and
2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
4 Any of the following:
4.1 All of the following:
4.1.1 PAH is confirmed by right heart catheterisation; and
4.1.2 A mean pulmonary artery pressure (PAPm) of greater than 20 mmHg; and
4.1.3 A pulmonary capillary wedge pressure (PCWP) that is less than or equal to 15 mmHg; and
4.1.4 Pulmonary vascular resistance (PVR) of at least 2 Wood Units or at least 160 International Units (dyn s cm-5); and
4.1.5 Any of the following:
4.1.5.1 PAH is non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines)†; or
4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool; or**
4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures.

Note:
† The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension
**** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.**

Changes to Section H Part II – effective 1 August 2023 (continued)

58 EPOPROSTENOL (amended restriction criteria)

➔ Inj 500 mcg vial	36.61	1	Veletri
➔ Inj 1.5 mg vial	73.21	1	Veletri

~~Restricted~~
~~Either:~~
~~1 For use in patients with a valid Special Authority approval for epoprostenol by the Pulmonary Arterial Hypertension Panel; or~~
~~2 In-hospital stabilisation in emergency situations.~~

Restricted
Initiation – Pulmonary arterial hypertension
Respiratory specialist or cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist.
Re-assessment required after 6 months
All of the following:
1 Patient has pulmonary arterial hypertension (PAH); and
2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV; and
4 Any of the following:
4.1 All of the following:
4.1.1 PAH has been confirmed by right heart catheterisation; and
4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm-5); and
4.1.5 Any of the following:
4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines)†; or
4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or**
4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
5 Either:
5.1 All of the following:
5.1.1 Epoprostenol is to be used as part of PAH dual therapy with either sildenafil or an endothelin receptor antagonist; and
5.1.2 Patient is presenting in NYHA/WHO functional class IV; and
5.1.3 Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool; or
5.2 Both:
5.2.1 Epoprostenol is to be used as PAH triple therapy; and
5.2.2 Any of the following:
5.2.2.1 Patient is on the lung transplant list; or
5.2.2.2 Patient is presenting in NYHA/WHO functional class IV; or
5.2.2.3 Both:

continued...

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

5.2.2.3.1 Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool; and

5.2.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

Continuation - Pulmonary arterial hypertension
Respiratory specialist, cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist or cardiologist. Approvals valid for 2 years where patient is continuing to derive benefit from epoprostenol treatment according to a validated PAH risk stratification tool.**
Note
† The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension
**** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.**

58 ILOPROST (amended restriction criteria)
➔ Nebuliser soln 10 mcg per ml, 2 ml
– **5% DV Mar-23 to 2025** ..... 185.03 30 **Vebulis**

Restricted
~~Initiation~~
~~Any of the following:~~
~~1 For use in patients with a valid Special Authority approval for iloprost by the Pulmonary Arterial Hypertension Panel; or~~
~~2 For diagnostic use in catheter laboratories; or~~
~~3 For use following mitral or tricuspid valve surgery; or~~
~~4 In-hospital stabilisation in emergency situations.~~

Initiation – Pulmonary arterial hypertension
Respiratory specialist or cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist.
Re-assessment required after 6 months
All of the following:
1 Patient has pulmonary arterial hypertension (PAH); and
2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
4 Any of the following:
4.1 All of the following:
4.1.1 PAH has been confirmed by right heart catheterisation; and
4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm-5); and
4.1.5 Any of the following:
4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines)†; or
4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool; or**

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or

4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or

4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures ; and

5 Any of the following:

5.1 Both

5.1.1 Iloprost is to be used as PAH monotherapy; and

5.1.2 Either:

5.1.2.1 Patient has experienced intolerable side effects on sildenafil and both the funded endothelin receptor antagonists (ie. Both bosentan and ambrisentan) or

5.1.2.2 Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to endothelin receptor antagonists; or

5.2 All of the following:

5.2.1 Iloprost is to be used as PAH dual therapy with either sildenafil or an endothelin receptor antagonist; and

5.2.2 Either:

5.2.2.1 Patient has an absolute contraindication to or has experienced intolerable side effects on sildenafil or

5.2.2.2 Patient has an absolute or relative contraindication to or experienced intolerable side effects with a funded endothelin receptor antagonist; and

5.2.3 Either:

5.2.3.1 Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool; or**

5.2.3.2 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would benefit from initial dual therapy; or

5.3 Both:

5.3.1 Iloprost is to be used as PAH triple therapy; and

5.3.2 Any of the following:

5.3.2.1 Patient is on the lung transplant list; or

5.3.2.2 Patient is presenting in NYHA/WHO functional class IV; or

5.3.2.3 Both:

5.3.2.3.1. Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool; and**

5.3.2.3.2. Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

Continuation - Pulmonary arterial hypertension

Respiratory specialist, cardiologist, rheumatologist, or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist.

Approvals valid for 2 years where patient is continuing to derive benefit from iloprost treatment according to a validated PAH risk stratification tool.**

Note

† The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension

**** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.**

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 August 2023 (continued)

DERMATOLOGICALS

63 HYDROCORTISONE (addition of note)
Crm 1%, 500 g – **5% DV Aug-23 to 2025** ..... 20.40 — 500 g — **Noumed**
Note: DV limit applies to the pack sizes of greater than 100 g.

INFECTIONS

87 DAPTOMYCIN (new listing and addition of PSS)
➔ Inj 500 mg vial – **5% DV Jan-24 to 2025** ..... 115.36 — 1 — **Daptomycin Dr Reddy's**
Note – Cubicin inj 500 mg vial to be delisted from 1 January 2024.

89 FLUCONAZOLE (↑ price)
➔ Oral liquid 50 mg per 5 ml..... 129.02 — 35 ml — Diflucan

MUSCULOSKELETAL SYSTEM

111 **INDOMETACIN [**INDOMETHACIN**]** (amended chemical name)
Cap 25 mg
Cap 50 mg
Cap long-acting 75 mg
Inj 1 mg vial
Suppos 100 mg

111 NAPROXEN (new listing)
Tab 250 mg – **5% DV Jan-22 to 2024** ..... 32.69 — 500 — **Noflam 250**
Note – this is a new Pharmacode listing, 2654458.

NERVOUS SYSTEM

119 TRAMADOL HYDROCHLORIDE (↑ price and addition of PSS)
Cap 50 mg – **5% DV Jan-24 to 2026**..... 3.33 — 100 — **Arrow-Tramadol**

129 CHLORPROMAZINE HYDROCHLORIDE
Tab 10 mg..... 14.83 — 100 — Largactil
Note: Largactil tab 10 mg to be delisted from 1 April 2024.

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

140 CAPECITABINE (new listing and addition of PSS)
Tab 150 mg – **5% DV Jan-24 to 2025** ..... 9.80 — 60 — **Capecitabine Viatris**
Tab 500 mg – **5% DV Jan-24 to 2025** ..... 46.50 — 120 — **Capecitabine Viatris**
Note – Capercit tab 150 mg and 500 mg to be delisted from 1 January 2024.

147 VENETOCLAX (new listing)
Tab 10 mg..... 13.68 — 2 — Venclexta
Note – Venclexta tab 10 mg, 14 tab pack to be delisted from 1 December 2023.

Changes to Section H Part II – effective 1 August 2023 (continued)

225 ATEZOLIZUMAB (amended restriction criteria – new criteria shown only)
➔ Inj 60 mg per ml, 20 ml vial ..... 9,503.00 1 Tecentriq

Restricted
Initiation – non-small cell lung cancer second line monotherapy
Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist
Re-assessment required after 4 months
All of the following:
1 Patient has locally advanced or metastatic non-small cell lung cancer; and
2 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
3 **For patients with non-squamous histology t**There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
4 Patient has an ECOG 0-2; and
5 Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
6 Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of **16** ~~12~~ weeks; and
7 Baseline measurement of overall tumour burden is documented clinically and radiologically.

227 PEMBROLIZUMAB (amended restriction criteria – new criteria shown only)
➔ Inj 25 mg per ml, 4 ml vial ..... 4,680.00 1 Keytruda

Restricted
Initiation – non-small cell lung cancer first-line monotherapy
Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist
Re-assessment required after 4 months
All of the following:
1 Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
2 Patient has not had chemotherapy for their disease in the palliative setting; and
3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
4 **For patients with non-squamous histology t**There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
5 Pembrolizumab to be used as monotherapy; and
6 Either:
  6.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain; or
  6.2 Both:
    6.2.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain; and
    6.2.2 Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
7 Patient has an ECOG 0-2; and
8 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of **16** ~~12~~ weeks; and
9 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Initiation – non-small cell lung cancer first-line combination therapy
Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist
Re-assessment required after 4 months
All of the following:
1 Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
2 The patient has not had chemotherapy for their disease in the palliative setting; and
3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 August 2023 (continued)

continued...

4 **For patients with non-squamous histology t**~~T~~here is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
5 Pembrolizumab to be used in combination with platinum-based chemotherapy; and
6 Patient has an ECOG 0-2; and
7 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of **16** ~~12~~ weeks; and
8 Baseline measurement of overall tumour burden is documented clinically and radiologically.

RESPIRATORY SYSTEM AND ALLERGIES

239 MONTELUKAST (new listing)
Tab 4 mg..... 3.10 28 Montelukast Viatris

SENSORY ORGANS

243 GENTAMICIN SULPHATE (new listing)
Eye drops 0.3%

247 PILOCARPINE ~~HYDROCHLORIDE~~ **NITRATE** (amended chemical name)
Eye drops 2%, single dose

➔ Restriction
(Brand) indicates a brand example only. It is not a contracted product.

Index
Pharmaceuticals and brands

Pharmaceutical Management Agency
Level 9, 40 Mercer Street, PO Box 10254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - www.pharmac.govt.nz
Email: enquiry@pharmac.govt.nz

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