

Pulmonary arterial hypertension

Initial authority application

Supporting information

When to use this form

This form must be completed by the treating physician from a designated centre.

You must lodge this form for a patient who is starting **initial** PBS subsidised treatment with one of the following:

Ambrisentan for the following conditions:

- i) World Health Organization (WHO) functional Class III or IV primary pulmonary hypertension (PPH)
- ii) WHO functional Class III or IV pulmonary arterial hypertension (PAH) secondary to connective tissue disease.

or

Bosentan monohydrate for the following conditions:

- i) WHO functional Class III or IV PPH
- ii) WHO functional Class III or IV PAH secondary to connective tissue disease
- iii) WHO functional Class III or IV PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology)

or

Epoprostenol sodium for the following conditions:

- i) WHO functional Class IV PPH
- ii) WHO functional Class IV PAH secondary to connective tissue disease

or

Iloprost trometamol for the following conditions:

- i) WHO functional Class IV PPH
- ii) WHO functional class IV PAH secondary to connective tissue disease
- iii) WHO functional Class III or IV drug induced PAH

or

Sildenafil citrate for the following conditions:

- i) WHO functional Class III PPH
- ii) WHO functional Class III PAH secondary to connective tissue disease

or

Tadalafil for the following conditions:

- i) WHO functional Class III PPH
- ii) WHO functional Class III PAH secondary to connective tissue disease

The term PAH agent refers to ambrisentan, bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or tadalafil only.

Patients are eligible for PBS subsidised treatment with one PAH agent at any time.

Patients with PPH secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70 per cent of that predicted are not eligible for PBS subsidised treatment.

Patients are not eligible to receive further PBS subsidised treatment with an agent to which they have previously failed to demonstrate stability or improvement.

Patients with **WHO functional Class III PPH** may be eligible to interchange between ambrisentan, bosentan monohydrate, sildenafil citrate and tadalafil, and epoprostenol sodium and iloprost trometamol (providing the patient has failed to respond to an alternate PBS subsidised PAH agent)

Patients with **PPH with WHO functional Class IV severity** may be eligible to interchange between ambrisentan, bosentan monohydrate, epoprostenol sodium and iloprost trometamol.

Patients with **WHO functional Class III PAH secondary to connective tissue disease** may be eligible to interchange between ambrisentan, bosentan monohydrate, sildenafil citrate and tadalafil, and epoprostenol sodium and iloprost trometamol (providing the patient has failed to respond to an alternate PBS subsidised PAH agent).

Patients with **WHO functional Class IV secondary to connective tissue disease** may be eligible to interchange between ambrisentan, bosentan monohydrate, epoprostenol sodium and iloprost trometamol.

Patients with **WHO functional class III or IV drug-induced PAH** are only eligible for treatment with iloprost trometamol. They may not interchange between agents.

Patients with **PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology)** are only eligible for treatment with bosentan monohydrate. They may not interchange between agents.

All applications must be in writing and must include sufficient information to determine the patient's eligibility. Results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a six minute walk test (6MWT) must be provided unless contraindicated on medical grounds. Details of prior vasodilator therapy must be provided for patients with WHO functional Class III with mean right arterial pressure (mRAP) \leq 8 mm Hg.

This application must be lodged within two months of the date of all assessments.

The information on this form is correct at the time of publishing and is subject to change.

Section 100 arrangements

These items are only available to a patient who is attending either:

- an approved private hospital
- a public participating hospital

or

- a public hospital

and is either:

- a day admitted patient
- a non-admitted patient

or

- a patient on discharge.

These items are not available as PBS benefits for in-patients of the hospital. The hospital provider number must be included on the application form.

Acknowledgements

The patient's and the prescriber's acknowledgements must be signed in front of a witness (over 18 years of age).

Authority prescription form

A completed authority prescription form must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

Initial treatment

Prescriptions for initial treatment with a PAH agent, other than bosentan, should be written for a maximum of six months of treatment.

For bosentan monohydrate only: Initial applications must include two written authority prescriptions, one for the first month of initiation therapy and another for the remaining five months of initial therapy.

Phone approvals

Under no circumstance will phone approvals be granted for complete authority applications, or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

The assessment of the patient's response to an initial course of treatment should be made after five months of treatment so that there is adequate time for a response to be demonstrated. A maximum of six months of treatment will be approved under this criterion.

Second and subsequent applications for continuing treatment must be submitted to Department of Human Services no later than one month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment.

Stopping treatment - bosentan only

For patients stopping treatment, phone approval will be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of one month. Call **1800 700 270** (call charges apply from mobile phones) and select option 1, between 8:00 am and 5:00 pm Australian Eastern Standard time, Monday to Friday.

For more information

If you need assistance completing this form or need more information call **1800 700 270** (call charges apply from mobile phones) and select option 1, between 8.00 am and 5.00 pm Australian Eastern Standard time, Monday to Friday or go to humanservices.gov.au/healthprofessionals and search for **Pulmonary arterial hypertension**

Returning your form(s)

Send the completed authority application form and completed authority prescription form(s) to:

Department of Human Services
Prior written approval of specialised drugs
Reply Paid 9826
Hobart TAS 7001

Filling in this form

Print in **BLOCK LETTERS**

Tick where applicable

Privacy notice

Centrelink, Medicare Australia, Child Support and CRS Australia are all part of the Australian Government Department of Human Services. Personal information held by Human Services is protected by law, including the *Privacy Act 1988*. The information provided on this form will be used to assess eligibility of the nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.

Pulmonary arterial hypertension

Initial authority application

Patient's details

1 Medicare/DVA card number

- - Ref no.

2 Mr Mrs Miss Ms Other

Family name

First given name

3 Date of birth

/ /

4 Patient's current weight

kg

Patient's acknowledgement

5 I acknowledge that PBS subsidised treatment with PAH agents for pulmonary arterial hypertension will stop if:

- subsequent testing demonstrates that I have failed to demonstrate stability or improvement to treatment
- I have failed treatment with the PAH agents for which I was eligible.

My prescriber has explained the nature of the ongoing monitoring and testing required to demonstrate an adequate response to therapy.

Parent/guardian's full name (if patient is under 18 years of age)

Patient's signature (or parent/guardian's signature if patient is under 18 years of age)

Date

/ /

Prescriber's details

Prescriber must be the treating physician from a designated centre.

6 Prescriber number

7 Family name

First given name

8 Work phone number

Alternative phone number

Fax number

Prescriber's acknowledgement

9 I have explained:

- the circumstances governing PBS subsidised treatment with PAH agents for pulmonary arterial hypertension
- the nature of the ongoing monitoring and testing required to demonstrate stability or improvement to treatment.

I believe these to be understood and accepted by the patient or the parent/guardian.

Prescriber's signature

Date

/ /

Witness's acknowledgement

10 I have witnessed the signatures of **BOTH** the patient and the prescriber.

Witness's full name (over 18 years of age)

Witness's signature

Date

/ /

Hospital details

11 Hospital name

12 Hospital provider number

Conditions and criteria

13 The patient is either:

- WHO functional Class III with $mRAP \leq 8$ mm Hg **Go to 14**
or
 WHO functional Class III with $mRAP > 8$ mm Hg **Go to 15**
or
 WHO functional Class IV **Go to 15**
or
 WHO functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) **Go to 17**

14 and has failed to achieve improvement/stability with prior vasodilator treatment for a minimum of six consecutive weeks treatment (RHC, ECHO, 6MWT assessments must be after the vasodilator treatment).

Name of drug

from / / to / /

Provide details of contraindication or intolerance to vasodilator treatment. Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Contraindication or intolerance

Go to 15

15 Indicate the patient's condition and the PAH agent requested:

- Primary pulmonary hypertension **Go to 16**
or
 Pulmonary arterial hypertension **Go to 17**

16 Primary pulmonary hypertension

- ambrisentan iloprost (WHO class IV only)
 bosentan sildenafil (WHO class III only)
 epoprostenol (WHO class IV only) tadalafil (WHO class III only)

Go to 18

17 Pulmonary arterial hypertension

- secondary to connective tissue disease
 ambrisentan iloprost (WHO class IV only)
 bosentan sildenafil (WHO class III only)
 epoprostenol (WHO class IV only) tadalafil (WHO class III only)
 drug induced
 iloprost
 associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology)
 bosentan

Go to 18

Test results

18 Provide test results for all three tests. These must be within two months of the date of this application.

RHC

Date of test

The composite of the RHC confirms the severity of PPH or PAH as per the eligibility criteria.

- No
 Yes

If test is unable to be performed, supply patient specific clinical reason for exemption.

ECHO

Date of test

The composite of the ECHO confirms the severity of PPH or PAH as per the eligibility criteria.

- No
 Yes

If test is unable to be performed, supply patient specific clinical reason for exemption.

6MWT

Date of test

Distance walked

 m

If test is unable to be performed, supply patient specific clinical reason for exemption.

Go to Attachments

Attachments



Attach a completed authority prescription form.

Prescriber's declaration

19 I declare that:

- the information on this form is correct.

Prescriber's signature

Date