

Chronic thromboembolic pulmonary hypertension – riociguat – initial authority application

Online PBS Authorities



Requesting PBS Authorities online provides an immediate assessment in real time.

For more information and how to access the **Online PBS Authorities** system, go to servicesaustralia.gov.au/hppbsauthorities

When to use this form

Use this form to apply for **initial** PBS-subsidised riociguat for patients 18 years or over with chronic thromboembolic pulmonary hypertension (CTEPH).

Important information

Initial applications to start PBS-subsidised treatment can be made in real time using the **Online PBS Authorities** system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Applications for **balance of supply** can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Under no circumstances will phone approvals be granted for CTEPH **initial** authority applications.

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

Continuing treatment

This form is ONLY for **initial** treatment.

After an authority application for **initial** treatment has been approved, applications for **continuing** treatment can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Section 100 arrangements for riociguat

This item is only available to a patient who is attending:

- an approved private hospital, **or**
- a public hospital

and is a:

- day admitted patient
- non-admitted patient, **or**
- patient on discharge.

This item is not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this authority form.

Treatment specifics

This authority application form must be completed by the treating physician from a centre with expertise in the management of CTEPH.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5mg increments at 2 week intervals to achieve up to a maximum of 2.5 mg 3 times daily based on the dosage recommendations for initiation of treatment in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for these prescriptions.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

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Online PBS Authorities



You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to servicesaustralia.gov.au/hppbsauthorities

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

7 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

8 Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

9 Is the patient, 18 years or over, being treated in a centre with expertise in the management of chronic thromboembolic pulmonary hypertension (CTEPH)?

No ☐

Yes ☐

10 Is this the sole PBS-subsidised therapy for this condition?

No ☐

Yes ☐

11 The patient has:

☐ WHO Functional Class II CTEPH

or

☐ WHO Functional Class III CTEPH

or

☐ WHO Functional Class IV CTEPH

12 The patient has CTEPH that is:

☐ inoperable by pulmonary endarterectomy

► **Go to 13**

or

☐ recurrent or persistent following pulmonary endarterectomy

► **Go to 14**



MCA0PB192 2506

13 As confirmation of evidence of **inoperable** CTEPH, the patient:

- ☐ has had a right heart catheterisation (RHC) demonstrating a pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation

PVR =

or

- ☐ was unable to complete a RHC due to right ventricular dysfunction, which has been demonstrated on echocardiogram.

and

- ☐ has a mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation

PAPmean = mmHg

Starting date of full anticoagulation (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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► Go to 15

14 As confirmation of evidence of **recurrent or persistent** CTEPH, the patient:

- ☐ has had a right heart catheterisation (RHC) demonstrating a pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy

PVR =

Date of pulmonary endarterectomy (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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or

- ☐ was unable to complete a RHC due to right ventricular dysfunction, which has been demonstrated on echocardiogram.

15 The patient has the following test result(s) in descending order of preference as per restriction requirements:

- ☐ RHC plus echocardiography (ECHO) plus 6 Minute Walk Test (6MWT)

or

- ☐ RHC plus ECHO (where 6MWT cannot be performed)

or

- ☐ RHC plus 6MWT (where ECHO cannot be performed)

or

- ☐ RHC (where ECHO and 6MWT cannot be performed)

or

- ☐ ECHO plus 6MWT (where RHC cannot be performed)

or

- ☐ ECHO (where 6MWT and RHC cannot be performed).

16 Provide available baseline test results (**no more than 2 months old** at the time of application):

- ☐ RHC composite assessment confirming the severity of CTEPH as per the eligibility criteria

Date of test (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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- ☐ ECHO composite assessment confirming the severity of CTEPH as per the eligibility criteria

Date of test (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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- ☐ 6MWT

Date of test (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Distance walked m

Checklist

- 17**  The relevant attachments need to be provided with this form.

- ☐ Details of the proposed prescription(s).

Privacy notice

18 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at servicesaustralia.gov.au/privacypolicy

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

19 I declare that:

- I am aware this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine
- I have informed the patient their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application
- I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction
- the information I have provided in this form is complete and correct.

I understand that:


- giving false or misleading information is a serious offence.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

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Prescriber's signature (**only** required if returning by post)



Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at **servicesaustralia.gov.au/hpos**
or
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001