

Paroxysmal nocturnal haemoglobinuria – pegcetacoplan – continuing or returning authority application

Online PBS Authorities



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

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 **continuing** or **returning** to PBS-subsidised pegcetacoplan for patients 18 years or over with paroxysmal nocturnal haemoglobinuria (PNH) for:

- first continuing treatment after the 'initial' or 'grandfather' authority approval
- subsequent treatment after the 'first continuing' or 'return' authority approval
- returning from PBS-subsidised eculizumab post pregnancy
- returning from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy.

Important information

Authority applications can be made 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.

Under no circumstances will phone approvals be granted for PNH **continuing** or **returning** authority applications.

C5 inhibitors are defined as eculizumab or ravulizumab.

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 **continuing** or **returning** treatment.

To return to pegcetacoplan treatment for the purpose of family planning, a patient may qualify more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, a patient may qualify once only in any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of this drug.

Section 100 arrangements for pegcetacoplan

This item is 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

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

For more information


Go to servicesaustralia.gov.au/healthprofessionals

- 13** Has the patient experienced clinical improvement or a stabilisation of the condition as a result of treatment with this drug?
 Yes
 No
- 14** During initiation of therapy, will the treatment be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks?
 Yes **Go to 20**
 No
- 15** Has the patient received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment criteria?
 Yes
 No
- 16** Is this treatment in combination with a C5 inhibitor?
 Yes
 No **Go to 20**
- 17** Has the patient previously received PBS-subsidised treatment with this drug under the 'First Continuing Treatment' or 'Return' criteria?
 Yes
 No
- 18** Has the patient experienced clinical improvement or a stabilisation of the condition as a result of treatment with this drug?
 Yes
 No
- 19** Is this treatment in combination with a C5 inhibitor?
 Yes **Ineligible**
 No **Go to 21**

20 Provide details of the following monitoring requirements

Test	Result	Date of test (DD MM YYYY)		
Haemoglobin (g/L)				
Platelets (x10 ⁹ /L)				
White Cell Count (x10 ⁹ /L)				
Reticulocytes (x10 ⁹ /L)				
Neutrophils (x10 ⁹ /L)				
Granulocyte clone size (%)				
Lactate Dehydrogenase (LDH)				
Upper limit of normal (ULN) for LDH as quoted by the reporting laboratory				
LDH : ULN ratio (in figures, rounded to one decimal place)				

Checklist

- 21**  The relevant attachments need to be provided with this form.
- Details of the proposed prescription(s).

Privacy notice

22 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

23 I declare that:

- I am aware that 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 that 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