Australian Government
Services Australia

medicare

PBS

Paroxysmal nocturnal haemoglobinuria – pegcetacoplan – initial 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 **initial** PBS-subsidised pegcetacoplan for patients 18 years or over with paroxysmal nocturnal haemoglobinuria (PNH).

Important information

Initial applications to start PBS-subsidised treatment 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 **initial** authority applications.

Complement 5 (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 **initial** treatment.

For **continuing** PBS-subsidised treatment, the patient must qualify under the **first continuing** or **subsequent continuing** treatment criteria.

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**

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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

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 The patient, 18 years or over, is being treated by a:

☐ haematologist

☐ non-specialist medical physician who has consulted a haematologist

10 Has the patient received prior treatment with this drug for this condition?

Yes ☐

No ☐

11 Has the patient received treatment with at least one of the C5 inhibitors for at least 3 months before initiating treatment with this drug?

Yes ☐ ***Go to 13***

No ☐

12 Had intolerance of severity necessitating permanent treatment withdrawal occurred?

Yes ☐

No ☐

13 The patient:

☐ has experienced an inadequate response to a C5 inhibitor demonstrated by a haemoglobin level of < 105 g/L

or

☐ is intolerant to C5 inhibitors as determined by the treating physician

14 Has the patient had PNH granulocyte clone size at least 10% within the last 3 months?

Yes ☐

No ☐

MCA0PB343 2412

15 During initiation of therapy, will the treatment be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks?

Yes ☐

No ☐

16 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

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 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)

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

If returning by post, print and sign by hand.

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

Reset form