Australian Government
Services Australia

medicare

PBS

Paroxysmal nocturnal haemoglobinuria – pegcetacoplan – initial grandfather 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 grandfather** PBS-subsidised pegcetacoplan for patients with paroxysmal nocturnal haemoglobinuria (PNH) who have received non-PBS-subsidised treatment with pegcetacoplan for the same condition prior to **1 December 2025.**

Important information

Initial grandfather 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 grandfather** 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 grandfather** treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the '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.

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 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 The patient is being treated by a:

- ☐ haematologist
- ☐ non-specialist medical physician who has consulted a haematologist

10 Has the patient received non-PBS-subsidised treatment for this condition with pegcetacoplan prior to 1 December 2025?

- Yes ☐
- No ☐

11 The patient is Complement 5 (C5) inhibitor:

- ☐ **inexperienced** ▶ ***Go to 16***
- ☐ **experienced** ▶ ***Go to 12***

12 Within the last 3 months prior to commencing non-PBS-subsidised treatment with this drug, did the patient have a PNH granulocyte clone size at least 10%?

- Yes ☐
- No ☐

13 Had the treatment been in combination with one C5 inhibitor for a period of 4 weeks during initiation of therapy?

- Yes ☐
- No ☐

14 Prior to initiating non-PBS-subsidised treatment with this drug, had the patient received treatment with at least one C5 inhibitor for at least 3 months?

- Yes ☐ ▶ ***Go to 19***
- No ☐ ▶ ***Go to 15***

MCA0PB345 2611

15 Had intolerance of severity necessitating permanent treatment withdrawal occurred?

Yes ☐ ***Go to 19***

No ☐

16 Prior to commencing non-PBS-subsidised treatment with this drug, did the patient receive any treatment for this condition?

Yes ☐

No ☐

17 Prior to commencing non-PBS-subsidised treatment with this drug, the patient had:

☐ a diagnosis of PNH established by flow cytometry

and

☐ a PNH granulocyte clone size ≥ 10%

and

☐ a raised lactate dehydrogenase (LDH) value at least 1.5 times the upper limit of normal (ULN).

18 Prior to commencing non-PBS-subsidised treatment with this drug, the patient had:

☐ experienced a thrombotic/embolic event which required anticoagulant therapy

or

☐ been transfused with at least 4 units of red blood cells in the previous 12 months

or

☐ debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH had been excluded

or

☐ a history of renal insufficiency, demonstrated by an eGFR ≤ 60 mL/min/1.73m^2, where causes other than PNH had been excluded

or

☐ recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia where causes other than PNH had been excluded

or

☐ chronic/recurrent anaemia, where causes other than haemolysis had been excluded, together with multiple haemoglobin measurements:

- ☐ not exceeding 70 g/L in the absence of anaemia symptoms

or

- ☐ not exceeding 100 g/L in addition to having anaemia symptoms.

19 Is this treatment the sole PBS-subsidised therapy for this condition?

Yes ☐

No ☐

20 Provide the 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)

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**
- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form