Australian Government
Services Australia

medicare

PBS

Paroxysmal nocturnal haemoglobinuria – eculizumab or ravulizumab – initial, switching, returning or balance of supply authority application

When to use this form

Use this form to apply for **initial** PBS-subsidised eculizumab or ravulizumab for patients with paroxysmal nocturnal haemoglobinuria (PNH) who are:

- new patients receiving induction doses
- switching to ravulizumab from eculizumab on the Australian Government's Life Saving Drugs Program (LSDP)
- returning from PBS-subsidised eculizumab for pregnancy or planning pregnancy
- switching from PBS-subsidised ravulizumab for pregnancy or planning pregnancy
- switching from PBS-subsidised pegcetacoplan for pregnancy or planning pregnancy
- returning from PBS-subsidised pegcetacoplan
- balance of supply – transitioning from non-PBS-subsidised eculizumab during induction.

Important information

Initial applications to start PBS-subsidised treatment must be 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 paroxysmal nocturnal haemoglobinuria **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 eculizumab and ravulizumab

These items are 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.

These items are 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 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's current weight

kg

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

8 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

9 Hospital provider number

Conditions and criteria

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

10 The patient is being treated by a:

☐ haematologist

☐ non-specialist medical physician who has consulted a haematologist

11 This application is for:

☐ eculizumab

☐ ravulizumab

12 Is this treatment in combination with another C5 inhibitor or pegcetacoplan?

No ☐

Yes ☐

MCA0PB327 2405

13 The patient:

☐ **has not** received prior treatment with this drug for this condition

▶ ***Go to 14***

or

☐ has previously received eculizumab for the treatment of PNH funded under the Australian Government's LSDP

▶ ***Go to 14***

or

☐ has received PBS-subsidised treatment with ravulizumab or pegcetacoplan for this condition

and

☐ is pregnant or planning pregnancy

▶ ***Go to 17***

or

☐ has received prior PBS-subsidised treatment with this drug for this condition

and

☐ has received prior PBS-subsidised treatment with eculizumab through the 'Initial 2 – switching from PBS-subsidised ravulizumab for pregnancy' criteria

▶ ***Go to 17***

or

☐ has received PBS-subsidised treatment with at least one C5 inhibitor for this condition

and

☐ has received PBS-subsidised treatment with pegcetacoplan for this condition and has developed resistance or intolerance to pegcetacoplan

▶ ***Go to 17***

or

☐ has received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022 and has received insufficient quantity to complete the induction treatment phase.

▶ ***Go to 14***

14 Prior to commencing treatment (including via LSDP) the patient has/had:

☐ a diagnosis of PNH established by flow cytometry

and

☐ a granulocyte clone size equal to or greater than 10%

and

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

15 Prior to commencing treatment (including via LSDP), the patient has/had:

☐ experienced a thrombotic/embolic event which required anticoagulant therapy

or

☐ been transfused with at least 4 units of red blood cells in the last 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 have been excluded

or

☐ a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded

or

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

or

☐ chronic/recurrent anaemia, where causes other than haemolysis have 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.

16 Provide the details of the following test results

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 quoted by reporting laboratory		
LDH : ULN ratio (in figures, rounded to one decimal place & must be at least 1.5)		

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