

Paroxysmal nocturnal haemoglobinuria – iptacopan – 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 iptacopan for patients with paroxysmal nocturnal haemoglobinuria (PNH) who have received non-PBS-subsidised treatment with iptacopan for the same condition prior to **1 November 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.

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)

Conditions and criteria

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

- 7 The patient is being treated by a:
 - ☐ haematologist
 - ☐ non-specialist medical physician who has consulted a haematologist
- 8 Has the patient received non-PBS-subsidised treatment with this drug for this condition prior to **1 November 2025**?
 - Yes ☐
 - No ☐
- 9 Within the 3 months prior to initiating non-PBS-subsidised treatment with this drug, did the patient have a documented PNH granulocyte clone size $\geq 10\%$?
 - Yes ☐
 - No ☐
- 10 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 12**
 - No ☐ **Go to 11**
- 11 Had intolerance of severity necessitating permanent treatment withdrawal occurred?
 - Yes ☐
 - No ☐
- 12 Prior to initiating non-PBS-subsidised treatment with this drug, the patient:
 - ☐ had experienced an inadequate response to a C5 inhibitor demonstrated by a haemoglobin level of < 105 g/L
 - or
 - ☐ was intolerant to C5 inhibitors as determined by the treating physician
- 13 Is this treatment the sole PBS-subsidised therapy for this condition?
 - Yes ☐
 - No ☐
- 14 Has the patient experienced clinical improvement or stabilisation of the condition as a result of treatment with this drug?
 - Yes ☐
 - No ☐



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15 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

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

☐ Details of the proposed prescription(s).

Privacy notice

- 17** 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

18 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