

Chronic treatment of Acute Hepatic Porphyria – givosiran – 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 givosiran for the chronic treatment of Acute Hepatic Porphyria (AHP) for patients at least 12 years of age.

Important information

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

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.

After an authority application for **initial** treatment has been approved, applications for **continuing** treatment can be made in real time 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.

Treatment specifics

At the time of the authority application, prescribers should request the appropriate number of vials for a single dose based on the patient's weight, as per the Therapeutic Goods Administration (TGA) approved 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 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

 kg

Prescriber's details

5 Prescriber number

6 Family name

First given name

7 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.

- 8 Is the treatment being initiated under the supervision of a healthcare professional experienced in the management of porphyria?
- Yes
- No
- 9 Does the patient, at least 12 years of age, have a confirmed diagnosis of Acute Hepatic Porphyria (AHP) based on clinical features (that include, but are not limited to, acute attacks of abdominal, back, chest, extremities, and/or limb pain)?
- Yes
- No
- 10 The patient has had at least 2 porphyria attacks (requiring hospitalisation, presentation at an emergency department, or medical intervention via a porphyria clinic) within the 6 months prior to:
- commencement of this drug
- or
- prophylactic treatment with gonadotropin-releasing hormone analogues or hemin
- 11 Provide details of porphyria attacks
- Baseline number of porphyria attacks within a defined 6 month period
-
- From (DD MM YYYY)
- To (DD MM YYYY)
- 12 The patient has had a previous result that showed a 4 times greater than the upper limit of normal (ULN) on one of the following tests:
- urinary porphobilinogen
- plasma porphobilinogen
- delta-aminolevulinic acid



MCA0PB399 2604

13 Provide pathology details

Pathology measurement that indicates 4 times greater than the ULN

Date of the pathology report (DD MM YYYY)

Unique identifying number/code of the pathology result

14 Has the patient previously undergone a liver transplant?

Yes

No

Checklist

15  The relevant attachments need to be provided with this form.

Details of the proposed prescription(s).

Privacy notice

16 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

17 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)

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