

Hereditary tyrosinaemia type 1 – nitisinone – initial authority application

Online PBS Authorities



Requesting PBS Authorities online provides an immediate assessment in real time.

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 nitisinone for patients with hereditary tyrosinaemia type 1.

Important information

Initial applications to start PBS-subsidised 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.

Under no circumstances will phone approvals be granted for hereditary tyrosinaemia type 1 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 by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Section 100 arrangements for nitisinone

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 authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment. A separate authority prescription form must be completed for each strength requested.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

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Online services



You do not need to complete this form if you use the
Online PBS Authorities system.

Go to servicesaustralia.gov.au/hppbsauthorities

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)

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 This application is for:

☐ nitisinone capsule

☐ nitisinone oral liquid for a patient under 18 years of age

11 The patient is being treated:

☐ by a physician with expertise in the management of hereditary tyrosinaemia type 1 (HT-1)

and

☐ in a centre with expertise in genetic metabolic disorders

12 Does the patient have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either urine or blood?

Yes ☐

No ☐

13 Have the diagnostic tests, including blood and/or urine test results confirming eligibility for treatment, been conducted within 12 months prior to the date of authority application?

Yes ☐

No ☐

14 Will the treatment be in combination with dietary restriction of tyrosine and phenylalanine?

Yes ☐

No ☐



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- 15 Is the patient suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug?

Yes ☐
No ☐

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
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001