

Primary hyperoxaluria type 1 – lumasiran – 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 servicessaustralia.gov.au/hppbsauthorities

When to use this form

Use this form to apply for **initial grandfather** PBS-subsidised lumasiran for patients with primary hyperoxaluria type 1 who have received non-PBS-subsidised treatment with lumasiran for the same condition prior to **1 October 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 primary hyperoxaluria type 1 **initial grandfather** 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 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. **Continuing** authority applications 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 based on the patient's weight, as per the TGA approved Product Information.

For more information

Go to servicessaustralia.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 The patient is being treated by:

- a nephrologist with experience in the management of hyperoxaluria
- a paediatrician with experience in the management of hyperoxaluria
- an authorised prescriber in consultation with one of the above specialty types

9 Has the patient received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2025?

- Yes
No

10 Is the condition primary hyperoxaluria type 1 confirmed by genetic testing?

- Yes
No

11 Has the patient previously undergone liver transplant for primary hyperoxaluria type 1?

- Yes
No

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

- undergone treatment with pyridoxine therapy

or

- a PH1 allele that is considered not responsive to pyridoxine therapy

or

- been contraindicated for pyridoxine therapy as determined by the treating or consulting clinician



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

urinary oxalate ≥ 0.70 mmol/24 h/1.73 m² measured by mean 24-h urinary oxalate excretion from a valid 24-h urine collection

or

urinary oxalate:creatinine ratio greater than the upper limit of normal based on age on at least two of three single-void collections during screening

or

clinical symptoms indicative of hyperoxaluria, such as nephrocalcinosis, renal stones, renal impairment or systemic oxalosis

14 Is the patient continuing to demonstrate clinical benefit as assessed by the treating physician?

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)

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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