

Fabry disease – migalastat – 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 migalastat for patients 12 years or over with Fabry disease who have received treatment with migalastat or Enzyme Replacement Therapy for the same condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to **1 September 2024**.

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 Fabry disease **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.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

After an authority application for **initial grandfather** 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.

Treatment specifics

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

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** Is the patient, 12 years or over, being treated by a physician with expertise in the management of Fabry disease?
- Yes
- No
- 8** Prior to **1 September 2024**, the patient has previously received treatment for this condition funded under the Australian Government's LSDP with:
- migalastat
- or
- Enzyme Replacement Therapy.
- 9** Prior to commencing treatment with this drug, did the patient have a documented migalastat amenable galactosidase alpha (GLA) gene variant?
- Yes
- No
- 10** Prior to commencing treatment with this drug, did the patient have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m²?
- Yes
- No

Checklist

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

Details of the proposed prescription(s).

Privacy notice

- 12** 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



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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

13 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