Australian Government
Services Australia

medicare

PBS

Fabry disease – migalastat or pegunigalsidase alfa – 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 Fabry disease treatment with:

- migalastat for patients at least 12 years of age who have received migalastat or Enzyme Replacement Therapy (ERT) for the same condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to **1 September 2024**
- pegunigalsidase alfa for patients who have received LSDP-funded ERT for the same condition prior to **1 August 2026**.

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.

Section 100 arrangements for pegunigalsidase alfa

This item is available to a patient who is attending:

- an approved private hospital
- a public participating 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

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)

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 Is the patient being treated by a physician with expertise in the management of Fabry disease?

- Yes ☐
- No ☐

11 This application is for:

- ☐ migalastat ▶ ***Go to 12***
- ☐ pegunigalsidase alfa ▶ ***Go to 13***

12 The patient, at least 12 years of age, has previously received treatment for this condition funded under the Australian Government's LSDP prior to **1 September 2024** with:

- ☐ this drug (migalastat)
- ☐ Enzyme Replacement Therapy

▶ ***Go to 14***

13 Has the patient previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's LSDP prior to **1 August 2026**?

- Yes ☐
- No ☐

▶ ***Go to 16***

14 Prior to commencing treatment with this drug, did the patient have a documented migalastat amenable galactosidase alpha (GLA) gene variant?

- Yes ☐
- No ☐

MCA0PB374 2608

15 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 ☐

16 Is this treatment the sole PBS-subsidised therapy for this condition?

Yes ☐
No ☐

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

18 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**

19 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)

If returning by post, print and sign by hand.

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

Reset form