Australian Government
Services Australia

medicare

PBS

Fabry disease – migalastat or pegunigalsidase alfa – 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:

- migalastat for patients at least 12 years of age with Fabry disease
- pegunigalsidase alfa for patients with Fabry disease.

Important information

Initial 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** 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 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

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

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 The patient has:

- ☐ documented deficiency of alpha-galactosidase enzyme activity in blood
- ☐ presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity.

12 This application is for:

- ☐ migalastat for a patient at least 12 years of age ▶ ***Go to 13***

or

- ☐ pegunigalsidase alfa ▶ ***Go to 15***

13 Does the patient have a documented migalastat amenable galactosidase alpha (GLA) gene variant?

- Yes ☐
- No ☐

14 Does the patient have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m²?

- Yes ☐
- No ☐

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15 The patient has:

- ☐ Fabry-related renal disease ▶ *Go to 16*
- ☐ Fabry-related cardiac disease ▶ *Go to 19*
- ☐ Fabry-related ischaemic disease ▶ *Go to 21*
- ☐ Fabry-related cerebrovascular disease as shown on objective testing with no other cause or risk factors identified ▶ *Go to 21*
- ☐ Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiseizure medications for peripheral neuropathy ▶ *Go to 21*
- ☐ significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies. ▶ *Go to 21*

16 The patient is:

- ☐ male ▶ *Go to 17*
- ☐ female ▶ *Go to 18*

17 The patient's disease has been confirmed by:

- ☐ abnormal albuminuria > 20 mcg/min determined by 2 separate samples at least 24 hours apart
- ☐ abnormal proteinuria > 150 mg/24 hours
- ☐ albumin : creatinine ratio > upper limit of normal in 2 separate samples at least 24 hours apart
- ☐ renal disease due to long-term accumulation of glycosphingolipids in the kidneys.

▶ *Go to 21*

18 The patient's disease has been confirmed by:

- ☐ proteinuria > 300 mg/24 hours with clinical evidence of progression
- ☐ renal disease due to long-term accumulation of glycosphingolipids in the kidneys.

▶ *Go to 21*

19 The patient's disease has been confirmed by:

- ☐ left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension ▶ *Go to 21*
- ☐ significant life-threatening arrhythmia or conduction defect ▶ *Go to 20*
- ☐ late gadolinium enhancement or a low T1 on cardiac MRI. ▶ *Go to 20*

20 The patient:

- ☐ has hypertension

  and

  - ☐ the hypertension has been treated optimally for at least 6 months prior to the first PBS authority application

  or

- ☐ does not have hypertension

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

- Yes ☐
- No ☐

Checklist

22

The relevant attachments need to be provided with this form.

- ☐ Details of the proposed prescription(s).

Privacy notice

23 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**

24 **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