



Australian Government

Department of Health  
and Aged Care

# Life Saving Drugs Program initial application form for subsidised treatment of Fabry Disease

## INITIAL APPLICATION FORM FOR TREATMENT OF FABRY DISEASE THROUGH THE LIFE SAVING DRUGS PROGRAM (LSDP)

### About this Program

The LSDP is administered by the Department of Health and Aged Care (the Department). Access to treatment for Fabry disease is provided in accordance with the *Guidelines for the treatment of Fabry disease through the Life Saving Drugs Program* (the Guidelines).

It is recommended that you read the Guidelines before completing this application form.

### Patient Administration

Patient applications are processed within 30 calendar days of the receipt of the complete package to support the application.

Should subsidised treatment be approved, it is the responsibility of the treating physician to ensure that the patient/patient's family is informed of:

- treatment arrangements, including approved dose
- the requirement to submit a reapplication for subsidised treatment through the LSDP by 1 May each year to request ongoing subsidised treatment
- the requirement to notify the LSDP in writing immediately if a change to the treatment location is planned, and
- the requirement to notify the LSDP in writing immediately if treatment is ceased.

### Filling in this form

The application form must be filled out by a treating physician with relevant specialist registration, with the consent of the patient or parent/guardian. The patient or their parent/ guardian is required to sign the application form to provide consent to the Department to collect personal information.

- Please complete electronically, print and sign; or
- Use black or blue pen and print in BLOCK LETTERS.

All pages of this application form must be completed and submitted. Incomplete applications will not be processed.

Ensure you have included:

- copies of all test results confirming the diagnosis of Fabry disease
- copies of any further data which may support the application
- a clinic letter to outline your patient's recent medical and surgical history and general description of their health status, and
- email the completed Excel spreadsheet in Excel format (available for download from [www.health.gov.au/lscp](http://www.health.gov.au/lscp)) to [lscp@health.gov.au](mailto:lscp@health.gov.au).

### Data Requirements

All assessments to support eligibility must be made **within 12 months prior to the date of application**.

### For more information

For more information go to the Department website [www.health.gov.au/lscp](http://www.health.gov.au/lscp)

If you need assistance completing this form, or for more information call **(02) 6289 2336**, Monday to Friday, between 9.00 am and 5.00 pm, Australian Eastern Standard Time.

### Submitting your form

Send the completed application form and all relevant attachments:

By email to: [lscp@health.gov.au](mailto:lscp@health.gov.au)

By fax to: **(02) 6289 8537**



### Treating physician's details

Prescriber number

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Given name

Family name

Work phone number

Mobile phone number

Email address

Hospital/Department

Postal address

Suburb

State

Post Code

### Clinic nurse's details

Given name

Family name

Work phone number

Email address

Hospital/Department

Postal address

Suburb

State

Post Code

### Pharmacist's details

Given name

Family name

Work phone number

Email address

Hospital/Department

Delivery address (for LSDP stock)

Suburb

State

Post Code

### Secondary pharmacy contact's details

Given name

Family name

Work phone number

Email address

**Dosing details**

Generic name of medicine requested:

If more than one medicine is available, provide clinical reason for choice of treatment:

Patient's weight

Patient's height

 kg

 cm

Dosage of medicine requested:  
(eg. x mg/kg/fortnight or 14 capsules for 28 day's supply)

Number of vials/capsules per dose (for ordering purposes)

To qualify for LSDP subsidised treatment, all of the following initial eligibility requirements must be met. **The treating physician must initial the box to confirm that the requirement is met.**

**1. Diagnosis of Fabry disease has been confirmed by:**

demonstration of specific deficiency of alpha-galactosidase enzyme activity in blood or white cells.

AND/OR

by the presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity.

**2. The patient meets (at least one of) the following criteria (please initial all that apply):**

**a) Fabry-related renal disease**

Male Fabry patients:

abnormal albumin (> 20µg/min ), as determined by 2 separate samples, at least 24 hours apart.

AND/OR

abnormal protein excretion (>150mg/24 hours).

AND/OR

albumin: creatinine ratio greater than upper limit of normal, in 2 separate samples, at least 24 hours apart.

AND/OR

renal disease due to long-term accumulation of glycosphingolipids in the kidneys.

Female Fabry patients:

proteinuria >300mg/24 hours with clinical evidence of progression.

AND/OR

renal disease due to long-term accumulation of glycosphingolipids in the kidneys.

**b) Fabry-related cardiac disease**

Left ventricular hypertrophy, as evidenced by cardiac MRI or echocardiogram data, in the absence of hypertension. (If hypertension is present, it should be treated optimally for at least 6 months prior to the submission of an application through this criterion)

AND/OR


Significant life threatening arrhythmia or conduction defect.

**c) Ischaemic vascular disease**

Shown on objective testing with no other cause or risk factors identified.

**d) Uncontrolled chronic pain**

Uncontrolled chronic pain despite the use of maximum doses of appropriate analgesia and antiepileptic medications for peripheral neuropathy.

 Attach copies of all test results as evidence.


**3. For migalastat only:** the patient has an amenable mutation and has been treated with ERT for at least 12 months; AND the patient is 16 years or older with an eGFR of 30 mL/m<sup>2</sup> or greater.

**4.** The patient has not presented with any of the conditions listed in the exclusion criteria.

**5.** The LSDP has been notified if the patient is participating in a clinical trial.

**6.** I have provided copies of all test results as evidence of initial eligibility.

**7.** I have provided the Excel spreadsheet in Excel format for Fabry disease, and have emailed this to the [lsdp@health.gov.au](mailto:lsdp@health.gov.au).

 Attach a clinic letter to outline your patient's recent medical and surgical history and general description of their health status.

## Treating physician's declaration

### I confirm that:

I am the treating physician of the patient as stated in this form, and have relevant specialist registration. I hereby apply for Australian Government subsidised access to treatment for Fabry disease through the LSDP on behalf of my patient.

### I declare that:

The information provided in this form is complete and correct.

I have attached copies of all relevant reports and forms, and completed the Excel spreadsheet for Fabry disease and emailed to [lsdp@health.gov.au](mailto:lsdp@health.gov.au) as evidence of initial eligibility.

To the best of my knowledge and belief, my patient is eligible to receive subsidised treatment with agalsidase alfa or agalsidase beta or migalstat through the LSDP in accordance with the Guidelines.

I am aware that the patient must be an Australian citizen or permanent Australian resident who qualifies for Medicare.

### I understand that:

I have an ongoing obligation to ensure that my patient continues to meet the eligibility criteria to receive subsidised treatment through the LSDP.

Making a false or misleading declaration is a serious offence and may lead to further investigations.

I must submit a separate reapplication for subsidised treatment through the LSDP by 1 May each year if I wish for my patient to continue to receive subsidised treatment.

### I agree that:

If I become aware that my patient no longer meets the eligibility criteria for subsidised access to treatment through the LSDP at any time, I will notify the Department immediately.

Treating physician full name

Treating physician signature

Treating physician sign date

## Application checklist

- Initial all boxes where applicable.
- Submit completed initial application form.
- Submit a clinic letter, less than 12 months old, to outline this patient's recent medical and surgical history and general description of their health status.
- Submit copies of all test results as evidence of initial eligibility (if no test results available, please state reasons).
- Email the completed Excel spreadsheet in Excel format for Fabry disease.

Clear form

Print form

Save form