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:

a) treatment arrangements, including approved dose
b) the requirement to submit a reapplication for subsidised treatment through the LSDP by 1 May each year to request ongoing subsidised treatment
c) the requirement to notify the LSDP in writing immediately if a change to the treatment location is planned, and
d) 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/lsdp) to lsdp@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/lsdp

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: **lsdp@health.gov.au**

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

Version date: September 2024

Privacy notice

The Department is collecting personal information about the patient identified on this application form to process this patient's initial application to receive subsidised treatment through the LSDP. If subsidised treatment through the LSDP is approved, the Department will continue to collect personal information about this patient in order to process a confirmation of ongoing eligibility.

If all of the personal information required is not provided, the Department will not be able to process the initial application to confirm eligibility to receive subsidised treatment through the LSDP.

The Department will disclose personal information to this patient's treating physician, pharmacists, clinical nurses and other health care professionals who may be involved in the administration of this patient's treatment.

The Department will disclose this patient's personal information including Medicare number to Services Australia in order to confirm Medicare eligibility and permanent Australia residency requirements.

'De-identified' personal information will be used for the purpose of the evaluation of the LSDP, which may include the provision of these data to third parties contracted by the Department for this purpose.

The Department has an APP privacy policy which can be read at https://www.health.gov.au/resources/publications/privacy-policy

The Department can be contacted by telephone on (02) 6289 1555 or freecall 1800 020 103 or by using the online enquiries form at www.health.gov.au

A copy of the APP privacy policy can be obtained by contacting the Department using the contact details set out above. The APP privacy policy contains information about:
· how to access personal information the Department holds and how to seek correction of it; and
· how to complain about a breach of the Australian Privacy Principles.

The Department is unlikely to disclose personal information to overseas recipients.

Patient's details

Medicare card number

										Ref no.	

Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Given Name

Family Name

Residential address

Suburb | State | Post Code

Date of Birth

Consent to collection of sensitive information for treatment and after cessation of treatment

I consent to the Department collecting genetic and health information about the patient identified on this application form for the purpose indicated above.

I consent to the Department requesting and obtaining sensitive information and supplemental information from my treating physician regarding the reason(s) for ceasing treatment including cause of death, if applicable.

If this information is not able to be obtained from my treating physician, I consent to the Department requesting and obtaining this information from other Government agencies and non-government organisations.

The information collected in this process is for the purpose of determining the cause of discontinuation of subsidised treatment.

Continuing eligibility for subsidised treatment with agalsidase alfa/agalsidase beta under the LSDP

I understand that:

- If I fail to comply with the associated monitoring and assessment requirements, without an acceptable reason to do so, I will no longer be eligible to receive subsidised treatment with agalsidase alfa/agalsidase beta through the LSDP.
- I understand that if treatment with agalsidase alfa and agalsidase beta does not result in a clinically meaningful effect, agalsidase alfa/agalsidase beta may be discontinued.

Signature

Patient ☐ Parent ☐ Guardian ☐ (tick one only)

Full name (print in BLOCK LETTERS)

Date

Treating physician's details

Prescriber number

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

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Dosing details

Generic name of medicine requested:

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

Patient's weight kg

Patient's height cm

Dosage of medicine requested: (eg. x mg/kg/fortnight)

Number of vials 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. The patient has not presented with any of the conditions listed in the exclusion criteria. ☐

4. The LSDP has been notified if the patient is participating in a clinical trial. ☐

5. I have provided copies of all test results as evidence of initial eligibility. ☐

6. I have provided the Excel spreadsheet in Excel format for Fabry disease, and have emailed this to the 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 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 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

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