



Australian Government

Department of Health
and Aged Care

Life Saving Drugs Program initial application form for subsidised treatment for Mucopolysaccharidosis Type IVA (MPS IVA)

INITIAL APPLICATION FORM FOR TREATMENT OF MPS IVA 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 MPS IVA is provided in accordance with the *Guidelines for the treatment of MPS IVA 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 data 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 relevant test results confirming the diagnosis of MPS IVA
- copies of any further data which may support the application
- a clinic letter less than 12 months old outlining your patient's recent medical and surgical history and general description of their health status
- email the completed Excel spreadsheet in Excel format (available for download from www.health.gov.au/lscp) to 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

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

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 treatment requested:

Patient's weight

 kg

Patient's height

 cm

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

Number of vials per dose (for ordering purposes)

Initial application

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 MPS IVA has been confirmed by the following tests:

a) elevated urine mucopolysaccharide substrate (uMPSs) analysis at baseline.

b) deficiency of *N*-acetylgalactosamine-6-sulfatase in white blood cells, or skin fibroblasts.

c) genetic testing for mutations in the GALNS gene or genetic testing has been requested and test results will be provided within 6 months.


2. Provisional eligibility for access to elosulfase alfa will be accorded on the basis of elevated uMPSs at baseline (and GALNS deficiency).

uMPSs quantitative analysis is to be provided at the following time points:

- i. Diagnosis (to establish a baseline)
- ii. 1 to 3 months post initiation to treatment
- iii. If a 20% reduction is not shown at (2ii) then at 6 months post initiation to treatment.

3. I agree to provide updated uMPSs quantitative analysis results at 1 to 3 months, and if required at 6 months post initiation to treatment, and will email this to lsdp@health.gov.au.

4. I agree that if a 20% reduction from baseline in uMPSs has not been demonstrated by 6 months post-treatment initiation, I will submit a clinic letter to the LSDP providing alternative measures to demonstrate how the patient is responding to therapy, including any relevant documentation for the LSDP's assessment.


 Attach copies of all test results as supporting evidence containing date of diagnosis.

5. The patient does not have any of the conditions listed in the exclusion criteria.

6. have provided copies of all relevant test results.

7. I have advised the LSDP if the patient is participating in a clinical trial.

8. I have provided the completed Excel spreadsheet in Excel format for MPS IVA, and have emailed this to 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 MPS IVA through the LSDP on behalf of my patient.

I declare that:

The information provided in this form is complete and correct.

To the best of my knowledge, my patient is eligible to receive subsidised treatment with elosulfase alfa 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:

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's full name

Treating physician's signature

Date

Application checklist

- Initial all boxes where applicable.
- Submit completed initial application form.
- Submit a clinic letter to outline this patient's recent medical and surgical history and general description of their health status.
- Submit copies of all relevant test results as evidence of initial eligibility.
- Email the completed Excel spreadsheet in Excel format for MPS IVA.