



Life Saving Drugs Program reapplication form for ongoing subsidised treatment for Mucopolysaccharidosis Type VI (MPS VI)

REAPPLICATION FORM FOR ONGOING TREATMENT OF MPS VI THROUGH THE LIFE SAVING DRUGS PROGRAM (LSDP)

Patient ID: MPS VI

Annual reapplication

To qualify for ongoing LSDP subsidised treatment, the following ongoing eligibility requirements must be met.


The treating physician must initial the box to confirm that the requirement is met.

- 1. The patient continues to meet the general eligibility requirements.
- 2. The patient has demonstrated clinical improvement or stabilisation of MPS VI.
- 3. The therapy has relieved the symptoms of disease that originally resulted in the patient being approved for subsidised treatment.
- 4. The patient has not experienced severe infusion-related reactions (not preventable by appropriate pre-medication and/or adjustment of infusion rates).
- 5. The patient has not developed significant learning difficulties and/or neuropathic involvement with their disease.
- 6. The patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by ERT.
- 7. The patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT.
- 8. The patient has not developed any of the conditions listed in the exclusion criteria.
- 9. I have provided copies of all test results as evidence of ongoing eligibility.

10. I have provided the completed Excel spreadsheet in Excel format for MPS VI, and have emailed to lsdp@health.gov.au

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

12. In my professional opinion, the patient is now unresponsive to treatment and / or has developed an irreversible complication or another severe disease. I have discussed my recommendation with the patient that he / she withdraw / be withdrawn from ERT. Full supportive care will be provided.

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

LSDP reapplication form for ongoing subsidised treatment for MPS VI

Privacy notice

The Department is collecting personal information about the patient identified on this reapplication form to process this patient's reapplication 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 reapplication 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 Australian Privacy Principles (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

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 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 galsulfase 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 galsulfase through the LSDP.
- I understand that if treatment with galsulfase does not result in a clinically meaningful effect, galsulfase may be discontinued.

Signature

Patient Parent Guardian (tick one only)

Full name (print in BLOCK LETTERS)

Date

Dosing details

Generic name of medicine requested:

Patient's weight

 kg

Patient's height

 cm

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

Number of vials per dose (for ordering purposes)

Is this a dose change for the patient?

Yes, this is a dose change

No dose change

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 reapply for Australian Government subsidised access to treatment for MPS VI 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, completed the Excel spreadsheet for MPS VI and emailed to lsdp@health.gov.au as evidence of ongoing eligibility.

To the best of my knowledge and belief, my patient continues to be eligible to receive subsidised treatment with galsulfase through the LSDP in accordance with the Guidelines.

I am aware that the patient must be an Australian citizen or permanent Australian resident who continues to qualify 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 form 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

Reapplication checklist

- Initial all boxes where applicable.
- Submit completed reapplication form.
- Submit copies of all test results as evidence of ongoing eligibility (if no test results available, please state reason).
- Email the completed Excel spreadsheet in Excel format for MPS VI.
- 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.