



# Life Saving Drugs Program reapplication form for ongoing subsidised treatment for infantile-onset or late-onset Pompe disease

## REAPPLICATION FORM FOR ONGOING TREATMENT OF INFANTILE-ONSET OR LATE-ONSET POMPE DISEASE THROUGH THE LIFE SAVING DRUGS PROGRAM (LSDP)


Patient ID:


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 infantile-onset or late-onset Pompe disease.
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 developed evidence of disease progression despite regular therapy, including but not limited to the development of the need for 24 hour invasive ventilation, for a period of 14 days or greater, provided that:
  - the cardiorespiratory failure is progressive
  - the requirement for ventilation is not due to a potentially reversible problem such as infection and
  - muscle tone is so poor that there is no useful movement.
5. For late-onset Pompe disease patients aged 18 years and over a decline of less than 20% versus prior year on 6MWT\*.
6. For late-onset Pompe disease patients aged 18 years and over a decline of less than 10% versus prior year on erect FVC.

\*For late-onset Pompe disease patients receiving alglucosidase alfa (Myozyme®) before 1 September 2015 this requirement is not applied.

7. The patient has not developed a life threatening complication which would compromise the effectiveness or benefit from continued ERT, including the patient has severe infusion-related reactions or antibody-related reactions which are not preventable or controlled by appropriate pre-medication and/or adjustment of infusion rates.
8. The patient does not have another life threatening or severe disease where the prognosis is unlikely to be influenced by ERT.
9. The patient is not a current smoker.
10. The patient does not have another medical condition that might reasonably be expected to compromise a response to ERT.
11. I have provided copies of all test results as evidence of ongoing eligibility.
12. I have advised the LSDP if the patient is participating in a clinical trial.
13. I have provided the completed Excel spreadsheet in excel format for infantile-onset or late-onset Pompe disease, and emailed to [lsdp@health.gov.au](mailto:lsdp@health.gov.au)
14. 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.

 Attach copies of all test results as evidence.



## 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 infantile-onset or late-onset Pompe 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, completed the Excel spreadsheet for infantile-onset or late-onset Pompe disease and emailed to [lsdp@health.gov.au](mailto: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 alglucosidase alfa or avalglucosidase 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 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 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

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 reasons).
- Email the completed Excel spreadsheet in Excel format for infantile-onset or late-onset Pompe disease.
- Submit a clinic letter to outline this patient's recent medical and surgical history and general description of their health status.

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