



Australian Government

Department of Health
and Aged Care

Life Saving Drugs Program Reapplication Form for Ongoing Subsidised Treatment of Late-Infantile Onset Batten (CLN2 disease)

REAPPLICATION FORM FOR ONGOING TREATMENT OF CLN2 DISEASE THROUGH THE LIFE SAVING DRUGS PROGRAM (LSDP)

Patient ID: CLN2

ONGOING ELIGIBILITY REQUIREMENTS

By 1 May every year, the treating physician must submit a completed reapplication form to the LSDP should they wish their patients to continue to receive subsidised treatment through the LSDP.


The reapplication form must demonstrate clinical stabilisation or slowing of progression of the patient's condition, and evidence to support ongoing eligibility for the treatment of CLN2 disease must be provided. Subsidised treatment may continue unless one or more of the following situations apply:

- 1. The patient continues to meet the general eligibility requirements.
- 2. The patient displays stabilisation or slowed progression of CLN2 disease as demonstrated by the ML score provided.

Date of assessment:

Domain	Score	ML (Study 201 and 202)	Score
Motor	3	Grossly normal gait. No prominent ataxia, no pathologic falls	
	2	Independent gait, as defined by ability to walk without support for 10 steps. Will have obvious instability, and may have intermittent falls	
	1	Requires external assistance to walk, or can crawl only	
	0	Can no longer walk or crawl	
Language	3	Apparently normal language. Intelligible and grossly age appropriate. No decline noted yet	
	2	Language has become recognizably abnormal: some intelligible words, may form short sentences to convey concepts, requests, or needs. This score signifies a decline from a previous level of ability (from the individual maximum reached by the child)	
	1	Hardly understandable. Few intelligible words	
	0	No intelligible words or vocalizations	
		Total Score	

- 4. The patient has not developed any of the conditions listed in the exclusion criteria.
- 5. The patient has not experienced severe infusion related reactions (not preventable/manageable by appropriate pre-medication and/or adjustment of infusion rates).
- 6. The patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by cerliponase alfa.
- 7. The patient has not developed another medical condition that might reasonably be expected to compromise a response to cerliponase alfa
- 8. The LSDP have been notified if the patient is participating in a clinical trial.
- 9. I have provided data as evidence of ongoing eligibility for CLN2 disease.

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

- 10. 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 they withdraw / be withdrawn from ERT. Full supportive care will be provided.

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 CLN2 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 CLN2 disease 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 cerliponase 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.

I have an ongoing obligation to report a sustained decline ≥ 2 points in the ML score to the Department over any continuous 48 week period during the course of their treatment to the Department.

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

Reapplication checklist

Initial all boxes where applicable.

Sign the declaration for ongoing eligibility.

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. List the patient's medications including name, route, dose, frequency and indication.

Submit data as evidence of ongoing eligibility, with the completed reapplication form.

Submit the completed Excel spreadsheet in Excel format for CLN2 disease.

Print form

Save form

Reset form