



Australian Government

Department of Health  
and Aged Care

# Life Saving Drugs Program initial application form for subsidised treatment for Late-Infantile Onset Batten Disease (CLN2 disease)

## INITIAL APPLICATION FORM FOR TREATMENT OF CLN2 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 CLN2 disease is provided in accordance with the *Guidelines for the treatment of CLN2 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 CLN2 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/lscp](http://www.health.gov.au/lscp)) to [lscp@health.gov.au](mailto: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](http://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](mailto: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

Fax number

Email address

Hospital/Department

Postal address

Suburb

State

Post Code

### Pharmacist's details

Given name

Family name

Work phone number

Fax 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 requested:

Patient's age:

Patient's weight: (kg)

Refer to CLN2 guidelines for age based dosage.

Dosage of medicine requested: (mg/every other week)


**General Eligibility**

To qualify for LSDP subsidised treatment, the following requirements must be met. The treating physician must initial the box to confirm that the requirement is met.


1. The patient is not suffering from any other medical condition, including complications or sequelae of the primary condition that might compromise the effectiveness of medicine treatment.

2. Diagnosis of CLN2 disease has been confirmed by a deficiency of Tripeptidyl Peptidase 1 (TPP1) in white blood cells, or skin fibroblasts.

3. Genetic testing for mutations in the CLN2 disease gene or genetic testing has been requested and test results will be provided within 2 months.

 If Yes - Attach supporting evidence. This must state the patient's date of diagnosis

4. Has the patient previously been treated with cerliponase alfa?  No  Yes

 If Yes - Attach evidence containing details of previous treatment.

5. Motor-Language (ML) score:


Indicate the patient's ML score in the following table. Individual scores and total score for motor and language must be completed.

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	

6. The patient has not presented with any of the conditions listed in the exclusion criteria.

7. Is the patient currently treated with other medications?  No  Yes

 If Yes - Attach medication list which includes: medication name, route, dose, frequency and indication.

## 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 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](mailto: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 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 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.

I have an ongoing obligation to report a sustained decline  $\geq 2$  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

## Application checklist

- Initial all boxes where applicable.
- Submit the completed ML scoring table.
- Submit the completed initial application form.
- Submit a recent clinic letter (no more 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 reason).
- Email the completed Excel spreadsheet in Excel format for CLN2

Print form

Save form

Clear form