HIGHMARK HEALTH OPTIONS

Updated: 05/2025
DMMA Approved: 05/2025

Request for Prior Authorization for Brineura (cerliponase alfa)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Brineura (cerliponase alfa) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Brineura (cerliponase alfa) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) and the following criteria is met:

- Must be prescribed by, or in consultation with, a neurologist or physician that specializes in the treatment of NCL diseases
- Must be age appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- Confirmation of a CLN2 diagnosis by submission of one of the following:
    - laboratory testing demonstrating deficient TPP1 enzyme activity
    - molecular analysis that has detected two pathogenic variants/mutations in the TPP1/CLN2 gene
- Member must have mild to moderate disease documented by all of the following on the Hamburg CLN2 Clinical Rating Scale (See Attachment I for Hamburg CLN2 Disease Clinical Rating Scale used in clinical trials):
    - A total baseline score of 3-6
    - A motor domain score of at least 1
    - A language domain score of at least 1
- Medication is being used to slow the loss of ambulation **AND** documentation indicates there is ambulatory function that can be preserved (e.g., not immobile)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice
- **Initial Duration of Approval:** 12 months

- **Reauthorization Criteria:**
    - Documentation the member's motor domain rating portion of the Hamburg CLN2 Clinical Rating score has remained stable or has not declined from baseline. (A decline is defined as having a sustained 2-category decline in motor function and language function score or an unreversed score of 0 in the motor domain of the CLN2 Clinical Rating Scale)
    - Member has motor (ambulatory) function that can be preserved (e.g., not immobile)
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

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BRINEURA (CERLIPONASE ALFA) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

BILLING INFORMATION

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE: _____)

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

PLACE OF SERVICE INFORMATION

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Late Infantile Neuronal Ceroid Lipofuscinosis type 2 (CLN2) ☐ Other: _____

How was the diagnosis confirmed (please submit chart documentation)?
☐ The member is deficient in TPP1 enzyme activity
☐ The member has two pathogenic variants/mutations in the TPP1/CLN2 gene

Please provide the following Hamburg CLN2 Disease Clinical Rating Scale scores for the member:
total combined baseline score: _____
baseline motor domain score: _____
baseline language domain score: _____

Does the member have ambulatory function that can be preserved? ☐ Yes ☐ No
Will this medication be used to slow the loss of ambulation? ☐ Yes ☐ No

REAUTHORIZATION

Does the member have ambulatory function that can be preserved? ☐ Yes ☐ No
Please provide the member's baseline CLN2 Clinical Rating motor domain score: _____ Date _____
Please provide the member's current CLN2 Clinical Rating motor domain score: _____ Date _____
Is the member being monitored for infection and cardiovascular adverse reactions (e.g., vital signs [blood pressure, heart rate] prior to, during, and post-infusion; ECG monitoring)? ☐ Yes ☐ No

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BRINEURA (CERLIPONASE ALFA)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date