



Updated: 06/2026  
DMMA Approved: 05/2026

**Request for Prior Authorization for Brineura (cerliponase alfa)**  
**Website Form – [www.highmarkhealthoptions.com](http://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.

**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? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> 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

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

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If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: (844) 325-6251 Mon – Fri 8 am to 7 pm**

**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**

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