



Updated: 06/2026
Approved: 05/2026

Request for Prior Authorization for Brineura (cerliponase alfa)
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

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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When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

**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: (833)-547-2030.**

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: 1-844-325-6251 Mon – Fri 8 am to 7 pm**

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: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE:
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:
How was the diagnosis confirmed (please submit chart documentation)?	
<input type="checkbox"/> The member is deficient in TPP1 enzyme activity	
<input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Will this medication be used to slow the loss of ambulation? <input type="checkbox"/> Yes <input type="checkbox"/> No	

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Does the member have ambulatory function that can be preserved? <input type="checkbox"/> Yes <input type="checkbox"/> 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)? <input type="checkbox"/> Yes <input type="checkbox"/> No

**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:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date

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