HIGHMARK WHOLECARE

Updated: 07/2025
PARP Approved: 06/2025

Prior Authorization Criteria

Brineura (Cerliponase alfa)

All requests for Brineura (Cerliponase alfa) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

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
- Confirmation of late infantile neuronal ceroid lipofuscinosis type 2 by 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
- Must be age appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based guidelines
- Documentation of a baseline evaluation, including an assessment of motor (ambulatory) function (see Attachment I for CLN2 Disease Clinical Rating Scale used in clinical trials)
- 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** requires documentation of the following:
    - Documentation the member is tolerating and receiving a clinical benefit from Brineura treatment based on the prescriber's clinical judgement (e.g., slowed loss of ambulation, motor skills maintained, etc.)
- **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.

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.

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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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty: ☐ Neurologist ☐ Other:	Office Contact:
State license #:	Office NPI
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:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, 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) **ICD-10 code:** _____

☐ Other: _____ **ICD-10 code:** _____

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
Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No Please provide documentation.
SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date