

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
- Member is at least 3 years of age or older
- 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.

**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: <input type="checkbox"/> Neurologist <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	

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: 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

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Prescribing Provider Signature	Date