

**Cerliponase alfa (Brineura®)**

**Place of Service**

Infusion Center  
Office Administration  
Outpatient Facility Administration  
Hospital Administration

HCPCS: J0567 per 1 mg

**Condition listed in policy (see criteria for details)**

- [Late infantile neuronal ceroid lipofuscinosis type 2 \(CLN2\) disease](#)

**AHFS therapeutic class:** Enzymes

**Mechanism of action:** Hydrolytic lysosomal N-terminal tripeptidyl peptidase

**(1) Special Instructions and pertinent Information**

**Covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax.

**(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for Brineura® (cerliponase alfa) must be sent for clinical review and receive authorization for both cerliponase alfa and for hospital admission prior to drug administration or claim payment.

**Late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease**

1. Diagnosis of symptomatic late infantile onset CLN2 disease, **AND**
2. Diagnosis by geneticist or pediatric neurologist, **AND**
3. Confirmed with documentation of either:
  - a. TPP1 enzyme deficiency, OR
  - b. Two pathogenic variants/mutations on separate parental alleles (i.e., in trans) in the TPP1/CLN2 gene,

**AND**

4. Patient is aged 3 years or older, **AND**
5. Patient is ambulatory

**Covered Doses**

Up to 300 mg ICV (intracerebroventricular) infusion every other week

**Coverage Period**

Indefinite

**ICD-10:**

E75.4

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for Brineura® (cerliponase alfa) must be sent for clinical review and receive authorization for both cerliponase alfa and for hospital admission prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- 150 mg/5 mL (single-dose vials)

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- Brineura® (cerliponase alfa) [Prescribing information]. Novato, CA. BioMarin Pharmaceutical Inc.; 3/2020.
- Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2 disease): Expert recommendations for early detection and laboratory diagnosis. Mol Genet Metab 2016; 119(1-2):160-7.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Mole SE, Schulz A, Badoe E, et al. Guidelines on the diagnosis, clinical assessments, treatment and management for CLN2 disease patients. Orphanet J Rare Dis 2021; 16:185.

**(7) Policy Update**

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*