cerliponase alfa (Brineura)

Commercial Medical Benefit Drug Policy

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Hydrolytic lysosomal N-terminal tripeptidyl peptidase
HCPCS:
J0567:Injection, cerliponase alfa, 1 mg
How Supplied:
150 mg/5 mL (single-dose vials)

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

- Neuronal Ceroid Lipofuscinosis Type 2 (CLN2) Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Neuronal Ceroid Lipofuscinosis Type 2 (CLN2) Disease
Meets medical necessity if all the following are met:
1. Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) disease
2. Diagnosed by geneticist or pediatric neurologist
3. Confirmed with documentation of either:
   a. TPP1 enzyme deficiency
   b. Two pathogenic variants/mutations on separate parental alleles (i.e., in trans) in the TPP1/CLN2 gene

Covered Doses:
Up to 300 mg given by intracerebroventricular infusion every other week

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:

E75.4

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Brineura (cerliponase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; July 2024.
3. Fietz M, AlSayed M, Burke D, et al. 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.
4. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
5. 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.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- Modify criteria based on expanded age indication *(Rationale: In July 2024, the FDA expanded approval of Brineura to patients from birth (previously 3 years or older) for neuronal CLN2 disease)*

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee