SmartHealth

Ascension

Cerliponase alfa

(Brineura®) J0567 (1 mg)

Covered with prior authorization

Cerliponase alfa (Brineura®) may be authorized when the following criteria are met:

- Individual is pediatric or adult individual (age ≥ 3 years); **AND**
- Individual has a confirmed diagnosis of Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2) disease via submission of documented:
    - Tripeptidyl peptidase 1 (TPP1) deficient enzyme activity; **OR**
    - Molecular analysis that has detected two pathogenic variant/mutations in the TPP1/CLN2 gene; **AND**
- Individual has the following on the CLN2 Clinical Rating Scale:
    - A. Aggregate total domain score of ≥ 3 or greater; **AND**
    - B. Score of ≥ 1 on each the motor and language domain; **AND**
- Prescribed by or in consultation with a specialist, preferably one specializing in genetics, metabolic disorders, pediatric neurology or physician that specializes in the treatment of CLN2 disease.

Exclusion criteria:

- Individual has Neuronal Ceroid Lipofuscinoses (NCLs) other than late infantile ceroid lipofuscinosis type 2 (CLN2)
- Individual has signs or symptoms of an unresolved infection on or near the site of insertion
- Individual has symptoms or a confirmed case of a central nervous system (CNS) infection
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and had a favorable response to treatment.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Cerliponase alfa (Brineura®) is a hydrolytic lysosomal N-terminal tripeptidyl peptidase, an enzyme replacement therapy indicated for treatment of pediatric individuals 2 years of age and older with neuronal ceroid lipofuscinosis type 2, a common type of Batten disease that results in loss of ambulation.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
3. Brineura® [Prescribing Information]. Novato, CA: BioMarin® Pharmaceutical Inc; 2023

Date	Summary of Changes
September 2021	Criteria for use summary developed by the Ascension Ambulatory Care Expert Review Panel.
January 2023	Criteria for use summary revised by the Ascension Medical Specialty Prior Authorization Team.
January 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.