

Pharmacy Medical Necessity Guidelines: Brineura™ (cerliponase alfa)

Effective: June 15, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	MM/ PRECERT
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>All plans except Tufts Health Public Plans: Precert: 617.972.9409</p> <p>Tufts Health Public Plans: MM: 888.415.9055</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Brineura (cerliponase alfa) is a hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

COVERAGE GUIDELINES

The plan may authorize coverage of Brineura (cerliponase alfa) for Members when all of the following criteria are met:

Initial therapy

1. Documented diagnosis of Late Infantile Neuronal Ceroid Lipofuscinosis type 2, confirmed by TPP1 deficiency
- AND**
2. The prescribing provider is a neurologist
- AND**
3. The Member is at least 3 years of age
- AND**
4. Documentation of a combined Motor plus Language domain CLN2 Clinical Rating Scale score of <6
- AND**
5. Documentation of a score of at least a 1 in the Motor domain of the CLN2 Clinical Rating Scale

Reauthorization Criteria

1. Documented diagnosis of Late Infantile Neuronal Ceroid Lipofuscinosis type 2, confirmed by TPP1 deficiency
- AND**
2. The prescribing provider is a neurologist
- AND**
3. The Member is at least 3 years of age
- AND**
4. Documentation of at least a 1 in the Motor domain of the CLN2 Clinical Rating Scale

LIMITATIONS

- Initial approval will be limited to 6 months. Reauthorization of Brineura (cerliponase alfa) will be provided in 6-month intervals.
- Members new to the plan stable on Brineura (cerliponase alfa) should be reviewed against Reauthorization Criteria.

- Brineura (cerliponase alfa) will not be approved for other forms of Neuronal Ceroid Lipofuscinosis.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0567	Injection, cerliponase alfa, 1 mg

REFERENCES

1. Brineura (cerliponase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; December 2018.
2. Steinfeld R, Heim P, von Gregory H, et al. Late infantile neuronal ceroid lipofuscinosis: quantitative description of the clinical course in patients with CLN2 mutations. *Am J Med Genet.* 2002;112:347-354.
3. Williams RE, Adams HR, Blohm M, Cohen-Pfeffer JL, de Los Reyes E, Denecke J, et al. Management strategies for CLN2 Disease. *Pediatr Neurol.* 2017 Apr;69:102-112.

APPROVAL HISTORY

December 12, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2018: Administrative update: Added new C code C9014 to Medical Necessity Guideline.
2. August 7, 2018: No changes
3. January 1, 2019: Administrative update: added new J code (J0567) to Medical Necessity Guideline and removed expired C code C9014 from Medical Necessity Guideline.
4. August 13, 2019: No changes
5. June 9, 2020: Administrative update to modify duration of approval Limitations to "Initial approval will be limited to 6 months. Reauthorization of Brineura (cerliponase alfa) will be provided in 6-month intervals" and "Members new to the plan stable on Brineura (cerliponase alfa) should be reviewed against Reauthorization Criteria."

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

[Provider Services](#)