Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Brineura™ (cerliponase alfa)

Effective: March 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:
Commercial Products
☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products
☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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 pediatric patients with neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Brineura for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of neuronal ceroid lipofuscinosis type 2 disease, confirmed by tripeptidyl peptidase 1 (TPP1) enzyme assay or genetic testing

AND

2. The prescribing provider is a neurologist

AND

3. Documentation of a combined Motor plus Language domain CLN2 Clinical Rating Scale score of less than 6

AND

4. Documentation of a score of at least 1 in the Motor domain of the CLN2 Clinical Rating Scale

Reauthorization Criteria

1. Documented diagnosis of neuronal ceroid lipofuscinosis type 2 disease, confirmed by tripeptidyl peptidase 1 (TPP1) enzyme assay or genetic testing

AND

2. The prescribing provider is a neurologist

AND

3. Documentation of at least 1 in the Motor domain of the CLN2 Clinical Rating Scale

Limitations

- Initial approval will be limited to 6 months. Reauthorization of Brineura will be provided in 12-month intervals.
- Members new to the plan stable on Brineura should be reviewed against Reauthorization Criteria.
- Brineura (cerliponase alfa) will not be approved for other forms of Neuronal Ceroid Lipofuscinosis.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0567	Injection, cerliponase alfa, 1 mg

References

1. Brineura (cerliponase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; July 2024.
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 mutation s. 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.
4. Mole SE, et al. Guidelines on the diagnosis, clinical assessments, treatment and management for CLN2 disease patients. Orphanet Journal of Rare Diseases. 2021;16(185):2-19.
5. 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. *Molecular Genetics and Metabolism*. 2016 (11): 160-167.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: Removed the requirement The Member does not have acute intraventricular access device-related complications (e.g., leakage, device failure, or device-related infection) or ventriculoperitoneal shunts. Removed the Limitation Brineura (cerliponase alfa) will not be approved for other forms of Neuronal Ceroid Lipofuscinosis (effective 12/1/2023).
- January 9, 2024: No changes. Added Tufts Health Together to the Medical Necessity Guideline (effective 2/1/2024).
- January 14, 2025: Removed age requirements and updated diagnosis requirements to align with updated package labeling (eff 2/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- February 10, 2026: no changes. Administrative update: Removed Carelink from template.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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