Mass General Brigham
Health Plan

Brineura (cerliponase alfa)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	**N/A**		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all the following criteria are met:

1. Documented diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2), confirmed by TPP1 deficiency or genetic testing
2. The prescribing provider is a neurologist

<u>Continuation of Therapy</u>
Requests for reauthorization will be approved when the following criteria are met:

1. Initial criteria are met.

Limitations
Initial approvals and reauthorizations will be for 6 months.

References

1. Brineura (cerliponase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; July 2024.
2. Schulz A, Ajayi T, Specchio N, de Los RE, Gissen P, Ballon D, et al. CLN2 Study Group. Study of intraventricular cerliponase Alfa for CLN2 disease. N Engl J Med. 2018;378:1898–1907. doi: 10.1056/NEJMoa1712649

Review History
04/17/2019 – Reviewed
05/20/2020 – Reviewed and Updated May P&T Mtg; added started and stabilized statement; updated 'Overview'; references updated. Effective 8/1/20.
10/09/2024 – Reviewed and updated at October P&T. Removed requirement that member is at least three years of age to align with updated FDA-approved package labeling. Effective 1/1/2025.