

Brineura (cerliponase alfa)
Effective 08/01/2020

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

Overview

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

Authorization may be granted for members who are currently receiving treatment with Brineura, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for Brineura when all the following criteria are met, and clinical documentation has been submitted:

1. Documented diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), confirmed by TPP1 deficiency or genetic testing
2. The prescribing provider is a neurologist
3. The member is at least 3 years of age

Continuation of Therapy

Reauthorizations may be approved when documentation is submitted that initial criteria have been met.

Limitations

Initial approvals and reauthorizations will be for 6 months.

References

1. Brineura (cerliponase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; December 2019.

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.

