Brineura (cerliponase alfa)
Effective 08/01/20

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 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.

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