



**Brineura (cerliponase alfa)
Effective August 1, 2019**

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
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.

FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy. All other indications are considered experimental/investigational and are not a covered benefit. the member has no exclusions to the prescribed therapy.

Coverage Guidelines

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

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 6-month intervals



References

1. Brineura (cerliponase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; December 2018.
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

04/17/19 – Reviewed

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