

Pharmacy Policy

Brineura

Policy Number: 9.301

Version Number: 2.0

Version Effective Date: 9/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Brineura (cerliponase alfa)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Ventriculoperitoneal shunts
Required Medical Information	<ol style="list-style-type: none"> 1. Member has been diagnosed with late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease confirmed by tripeptidyl peptidase (TPP1) deficiency (documentation required), AND 2. Member is over the age of 3; AND 3. Member is ambulatory
Age Restriction	3 years of age or older
Prescriber	Prescribed by or in consultation with a neurologist, a physician who specializes in genetics, or a

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Restriction	pediatrician with experience treating lysosomal storage diseases
Coverage Duration	12 months
Other criteria	Reauthorization: 1. initial criteria is met ; AND 2. There are no unacceptable toxicities; AND 3. Member has responded to therapy compared to pretreatment baseline as shown by improvement in motor function/milestones on the motor domain of the Hamburg CLN2 Clinical Rating Scale (see appendix for motor domain of the CLN2 Clinical Rating Scale)

Appendix:

The motor domain of the CLN2 Clinical Rating Scale is scored as follow: walks normally = 3, intermittent falls, clumsiness, obvious instability = 2, no unaided walking or crawling only = 1, immobile, mostly bedridden = 0.

Applicable Coding:

CODE	Description
J0567	Injection, cerliponase alfa, 1mg

Clinical Background Information and References

1. Brineura (cerliponase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; April 2017.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.079 Brineura policy retired, new policy created	1/1/2021	P&T Committee
5/13/2021	P&T Annual review: Updated initial criteria to require documentation of TPP1 deficiency and removed criteria pertaining to aseptic technique. Updated reauthorization criteria to include	9/1/2021	P&T Committee

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Policy Revisions History

	response to therapy		
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Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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