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Pharmacy Policy

Brineura

Policy Number: 9.301

Revision Number: R1

Version Effective Date: 1/1/2021

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, a form of Batten disease; AND 2. Member is over the age of 3; AND 3. Member is ambulatory; AND 4. Medication will be administered by, or under the direction of, a physician knowledgeable in intraventricular administration and aseptic technique will be strictly observed during preparation and administration.
Age	3 years of age or older

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Restriction	
Prescriber Restriction	Prescribed by or in consultation with a neurologist, a physician who specializes in genetics, or a pediatrician with experience treating lysosomal storage diseases
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Continues to meet initial review criteria; AND 2. There are no unacceptable toxicities; AND 3. Member is able to tolerate intraventricular infusions with documentation provided showing no adverse reactions (i.e., no hypersensitivity reaction to the infusion, stable vital signs during and post-infusion).

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	01/01/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	P&T Review: discontinued policy 9.079 and created a new policy for NH	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

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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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