Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 157.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Brineura (cerliponase alfa)

I. Policy:
Brineura (cerliponase alfa)

II. Purpose/Objective:
To provide a policy of coverage regarding Brineura (cerliponase alfa)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Brineura (cerliponase alfa) is a proenzyme that, once activated, cleaves tripeptides from the N-terminus of proteins. This leads to the breakdown of lysosomal storage materials that otherwise accumulate in patients with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), leading to progressive decline in motor function.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Brineura (cerliponase alfa) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that the prescription is written by a pediatric neurologist **AND**
- Medical record documentation that the patient is 3 years of age or older **AND**
- Medical record documentation of a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (LINCL) confirmed by the following test results:
    - Deficient TPP1 activity in leukocytes on the enzyme activity test **AND**
    - Pathogenic variant/mutation in the TPP1/CLN2 gene (note- may be absent in up to 20% of patients, but if present is confirmatory of diagnosis) **AND**
- Medical record documentation of the baseline score on the motor domain of the CLN2 clinical rating scale **AND**
- **For Commercial Lines of Business only**: Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility)

QUANTITY LIMIT: 2 doses per month (24 doses per year)

AUTHORIZATION DURATION: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require the following Reauthorization criteria are met:

- **For Medicaid Lines of Business only:** Medical record documentation that there is continued benefit from treatment based on the prescriber's professional judgment
- **For Commercial Lines of Business only**: Medical record documentation that patient remains to be ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility).

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/19/17

Revised: 11/8/17 (per DHS), 8/19/22 (Medicaid PARP statement)

Reviewed: 8/30/18, 8/29/19, 8/26/20, 8/20/21