Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 100.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Elelyso (taliglucerase alfa)

I. Policy:
Elelyso (taliglucerase alfa)

II. Purpose/Objective:
To provide a policy of coverage regarding Elelyso (taliglucerase 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
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. 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:
Elelyso (taliglucerase alfa) is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease.

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

Elelyso (taliglucerase alfa) will be considered medically necessary for the commercial, exchange, CHIP and Medicare lines of business when all of the following criteria are met:

Adult Patients:
- Age greater than or equal to 18 years **AND**
- Medical record documentation of a confirmed diagnosis of Type 1 Gaucher disease along with at least one of the following conditions:
    - anemia **OR**
    - thrombocytopenia **OR**
    - bone disease **OR**
    - hepatomegaly or splenomegaly **AND**
- Elelyso™ (taliglucerase alfa) is recommended by a metabolic specialist with experience in treating Gaucher disease

Pediatric Patients:
- Age between 4 and 17 years **AND**
- Medical record documentation of a confirmed diagnosis of Type 1 Gaucher disease along with at least one of the following symptoms:
    - Malnutrition **OR**
    - Growth retardation **OR**
    - Impaired psychomotor development **OR**
    - Fatigue **OR**
    - Anemia **OR**
    - thrombocytopenia **OR**
    - bone disease **OR**
    - hepatomegaly or splenomegaly **AND**
- Elelyso™ (taliglucerase alfa) is recommended by a metabolic specialist with experience in treating Gaucher disease

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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.

REFERENCES:

1. Elelyso [prescribing information]. New York, NY: Pfizer Labs; May 2023.
2. Wang RY, Bodamer OA, Watson MS, et al. Lysosomal storage diseases: Diagnostic confirmation and management of presymptomatic individuals. American College of Medical Genetics (ACMG). Generics in Medicine; 2011 May; 13(5):457-484 [cited 2023 Dec 27]. Available from: https://www.sciencedirect.com/science/article/pii/S1098360021047924?via%3Dihub
3. Charrow J, Andersson HC, Kaplan P, et al. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. The Journal of Pediatrics; 2004 Janurary; 144(1):112-120 [cited 2023 Dec 27]. Available from: https://www.sciencedirect.com/science/article/pii/S002234760300814X?via%3Dihub

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

Devised: 11/6/12

Revised: 1/20/15 (Added pediatric criteria), 5/8/17 (per DHS), 1/16/23 (LOB carve out), 12/31/23 (references added), 1/8/2024 (Medicaid business segment)

Reviewed: 3/14, 1/20/2015, 3/16, 3/30/17, 3/29/18, 2/28/19, 2/10/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23