Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 291.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Lamzede (velmanase alfa-tycv)

I. Policy:
Lamzede (velmanase alfa-tycv)

II. Purpose/Objective:
To provide a policy of coverage regarding Lamzede (velmanase alfa-tycv)

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:
Lamzede (velmanase alfa-tycv) binds to extracellular mannose-6-phosphate receptors and is transported to lysosomes, where it provides an exogenous source of alpha mannosidase. Alpha mannosidase degrades mannose-containing oligosaccharides. Lack of alpha mannosidase leads to the accumulation of mannose-rich oligosaccharides in tissue, which causes clinical symptoms associated with alpha-mannosidosis lysosomal storage disease.

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

Lamzede (velmanase alfa-tycv) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of alpha-mannosidosis supported by:
    - Enzyme assay demonstrating alpha-mannosidase activity less than 10% of normal activity (<0.54 nmol/min/mg)

    OR
    - Molecular genetic testing that reveals pathogenic variants in the MAN2B1 gene

    AND
- Medical record documentation that the patient is prescribed Lamzede (velmanase alfa-tycv) for the treatment of non-central nervous system manifestations of alpha-mannosidosis **AND**
- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

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 **12 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 (i.e., improvement or stabilization in motor function, improvement in forced vital capacity % (FVC), reduction in frequency of infections, etc.)

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: 7/18/23

Revised:

Reviewed: