Lamzede® (velmanase alfa-tycv)

Effective Date: 7/1/24
Medical Care Management Committee Approval: 4/25/24

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Lamzede® (velmanase alfa-tycv)product:

HCPCS Code	Description
J0217	Injection, velmanase alfa-tycv, 1 mg

Initial Coverage Criteria

Lamzede® (velmanase alfa-tycv) will be considered medically necessary for members meeting ALL of the following criteria:

1. Prescribed by or in consultation with a geneticist or metabolic specialist; AND
2. Diagnosis of alpha-mannosidosis confirmed by alpha mannosidase activity less than 10% of normal activity in leukocytes or fibroblasts; AND
3. Genetic testing confirming two pathogenic variants in Mannosidase Alpha Class 2B Member 1 (MAN2B1); AND
4. Member is exhibiting non-central nervous system manifestations of alpha-mannosidosis (e.g. progressive motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormalities, and immune deficiency)

Criteria for Continuation of Coverage

1. Member meets initial coverage criteria; AND

2. No unacceptable toxicity or adverse reactions to Lamzede; AND
3. Member demonstrates a beneficial response to therapy or stabilization of disease progression

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J0217	Injection, velmanase alfa-tycv, 1 mg

Diagnosis Code	Description
E77.1	Defects in glycoprotein degradation (Alpha-mannosidosis)

Policy Revision History

Status	Effective Date	Description
Baseline	7/1/24	Initial version of Lamzede Review Guideline