Medical Policy:

Lamzede (velmanase alfa-tycv), injection powder for solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.382	March 24, 2025	April 21, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Lamzede is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

- (Up to 49 kg) 1 mg/kg IV infused over a minimum of 60 minutes once weekly
- (50 kg or greater) 1 mg/kg IV infused at a maximum rate of 25 mL/hour once weekly

Max Units (per dose and over time) [HCPCS Unit]:

110 mg every 7 days

Guideline

I. INITIAL CRITERIA

1. **<u>Alpha-mannosidosis</u>.** Approve if the patient meets the following criteria:
   A. Patient has a confirmed diagnosis of alpha-mannosidosis, defined as alpha-mannosidase activity less than 10% of normal activity in blood leukocytes; **AND**
   B. Patient has biallelic pathogenic variants in Mannosidase Alpha Class 2B Member 1 (*MAN2B1*) as confirmed by mutation testing; **AND**
   C. Patient has non-central nervous system manifestations; **AND**
      <u>Note</u>: Examples of non-central nervous system manifestations include progressive motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormalities, and immune deficiency.
   D. The medication is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

II. RENEWAL CRITERIA

A. Patient continues to meet Initial Criteria; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include anaphylaxis and severe allergic or infusion associated reactions, etc.; **AND**
C. Patient has demonstrated a beneficial response to therapy or stabilization of disease

Applicable Procedure Codes

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

Applicable NDCs

Code	Description
10122-0180-XX	Lamzede (velmanase alfa-tycv) 10mg

ICD-10 Diagnoses

Code	Description
E77.1	Defects in glycoprotein degradation

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	03/24/2025	Annual Review: Updated description of the current ICD-10 code. No criteria changes.
EmblemHealth & ConnectiCare	2/5/2024	Annual Review: Updated Dosing limits, added renewal criteria, Initial Criteria: Added:" Patient has biallelic pathogenic variants in Mannosidase Alpha Class 2B Member 1 (*MAN2B1*) as confirmed by mutation testing; AND" Updated J code to add J0217 and removed J3590
EmblemHealth & ConnectiCare	4/21/2023	New Policy

References

1. Product Information: LAMZEDE® intravenous injection, velmanase alfa-tycv intravenous injection. Chiesi USA Inc (per FDA), Cary, NC, 2023.