AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Lamzede® (velmanase alfa-tycv) **(J0217) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage and Quantity Limit: Approved for a maximum of 1 mg/kg (actual body weight) administered by intravenous infusion no more frequently than every week.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

(Continued on next page)

- ❑ Member is at least 3 years of age
- ❑ Prescribed by or in consultation with a geneticist or metabolic specialist
- ❑ Member has a definitive diagnosis of alpha mannosidosis as confirmed by **ONE** of the following **(submit test results confirming diagnosis)**:
  - ❑ Identification of deficient acid alpha-mannosidase enzyme activity in peripheral blood leukocytes or other nucleated cells such as fibroblasts of <11% of normal activity
  - ❑ Identification of biallelic pathogenic variants in MAN2B1 by molecular genetic testing
- ❑ Provider must submit baseline serum oligosaccharides lab test results taken within the last 30 days
- ❑ Provider must submit baseline age-appropriate values for at least **ONE** of the following **(check all that apply)**. **NOTE: For very young members in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by-case basis.**
  - ❑ 6-minute walk test (6-MWT)
  - ❑ 3-minute stair climb test (3-MSCT)
  - ❑ Pulmonary function tests (e.g., forced vital capacity)
  - ❑ Motor function test [e.g., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2)]
- ❑ Member has a confirmed negative pregnancy test in females of reproductive potential
- ❑ Medication is being used to treat non-central nervous system manifestations of alpha mannosidosis (i.e., skeletal abnormalities, myopathy, motor function disturbances, immunodeficiency)
- ❑ Member does **NOT** have a history of hematopoietic stem cell transplant (HSCT)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., anaphylaxis and severe allergic or infusion associated reactions)
- ❑ Provider must submit current documentation that member has had a decrease in serum oligosaccharide concentration from baseline after initial authorization, or stabilization in concentration for subsequent reauthorizations, along with **ONE** of the following:
  - ❑ Stability or improvement in 6-minute walking test (6-MWT)
  - ❑ Stability or improvement in 3-minute stair climbing test (3-MSCT)
  - ❑ Stability or improvement in forced vital capacity (FVC) (% predicted)
  - ❑ Stabilization or slowing in the rate of disease progression or clinical decline

(Continued on next page)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration**: _____
  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.