Lamzede

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ Same as Requesting Provider
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ Same as Referring Provider ❑ Same as Requesting Provider
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*cm*

What is the ICD-10 code? _____

Site of Service Questions:

A. Where will this drug be administered?
- ❑ Ambulatory surgical, *skip to Clinical Questions*
- ❑ Off-campus Outpatient Hospital
- ❑ Physician office, *skip to Clinical Questions*
- ❑ Home infusion, *skip to Clinical Questions*
- ❑ On-campus Outpatient Hospital
- ❑ Pharmacy, *skip to Clinical Questions*

B. Is the patient less than 14 years of age? ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

C. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes - This is a continuation of an existing treatment.
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months). *If No, skip to Clinical Criteria Questions*

D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or

seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, Attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

E. Does the patient have laboratory confirmed anti-velmanase alfa-tycv antibodies? ***ACTION REQUIRED: If Yes, Attach supporting clinical documentation*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, Attach supporting clinical documentation.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: If Yes, Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? ***ACTION REQUIRED: If Yes, Attach supporting clinical documentation.*** ❑ Yes ❑ No

Clinical Criteria Questions:

1. What is the diagnosis?

❒ Alpha-mannosidosis, *Continue to #2*

❒ Other, *Continue to #2*

2. Is the patient currently receiving treatment with the requested drug?

❒ Yes, *Continue to #3*

❒ No, *Continue to #4*

Continuation

3. Has the patient demonstrated a response to therapy (e.g., improvement in 3-minute stair climbing test [3MSCT] from baseline, improvement in 6-minute walking test [6MWT] from baseline, improvement in forced vital capacity [FVC, % predicted] from baseline, reduction in serum or urine oligosaccharide concentration from baseline)? ***Action Required***: If Yes, attach documentation (e.g., chart notes, lab results) of a response to therapy (e.g., improvement in 3-minute stair climbing test [3MSCT] from baseline, improvement in 6-minute walking test [6MWT] from baseline, improvement in forced vital capacity [FVC, % predicted] from baseline, reduction in serum or urine oligosaccharide concentration from baseline)

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Initial

4. Will the requested drug be used for the treatment of non-CNS manifestations of alpha-mannosidosis?

❒ Yes, *Continue to #5*

❒ No, *Continue to #5*

5. Was the diagnosis confirmed by a documented deficiency of alpha-mannosidase activity as measured in blood leukocytes or fibroblasts? ***Action Required***: If Yes, attach alpha-mannosidase enzyme assay results supporting the diagnosis

❒ Yes, *No Further Questions*

❒ No, *Continue to #6*

6. Was the diagnosis confirmed by genetic testing documenting a mutation in the MAN2B1 gene? ***Action Required***: If Yes, attach genetic testing results supporting the diagnosis

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720