Physician Order/Prescription & Statement of Medical Necessity

Please fax completed form to Chiesi Total Care℠ staff at 1-855-929-2828.

PATIENT INFORMATION

Patient Name (Last, First) _____

Parent/Caregiver Name (if applicable) _____

Social Security # _____ - _____ - _____ Sex: ☐ Male ☐ Female Date of Birth _____/_____/_____ (mm/dd/yyyy)

Address _____ City _____ State _____ ZIP _____

Primary Phone (Required) _____ Cell Phone _____ Language: ☐ English ☐ Other _____

INSURANCE INFORMATION

☐ No Insurance

Primary Prescription	**Primary Medical**	**Secondary Medical**
Insurance _____	**Insurance** _____	**Insurance** _____
Policy Holder _____	Policy Holder _____	Policy Holder _____
Policy ID # _____	Policy ID # _____	Policy ID # _____
Group # _____	Group # _____	Group # _____
Phone _____	Phone _____	Phone _____

Please attach copies of patient insurance and prescription cards—front and back.

MEDICAL INFORMATION

Diagnosis: ☐ Alpha-mannosidosis (ICD E.77.1 Defects in glycoprotein degradation)

Height _____ inches or _____ cm Weight _____ lb or _____ kg Allergies: ☐ None ☐ Specify _____

Methods of Diagnosis (check all that apply): ☐ Enzyme Assay ☐ Genetic Testing

Please attach copies of medical history/physical summary, urine oligosaccharides, acid alpha-mannosidase activity in leukocytes, current medications, genetic testing results, and allergies.

LAMZEDE® (VELMANASE ALFA-TYCV) PRESCRIPTION/ORDER

Dosage Strength — Lamzede (velmanase alfa-tycv)

☐ NDC 10122-180-02: **1 single-use 10-mg vial**

Dose _____ mg/kg Route of Administration IV _____ Frequency* _____ Number of Refills† _____ Patient Infusion Rate _____

*The recommended dosage is 1 mg/kg (actual body weight) administered every week as an intravenous infusion. †28-day supply will be distributed.

Please list any additional treatment information, including follow-up evaluations: _____

_____

SITE OF SERVICE

Preferred Site of Infusion

☐ Prescribing physician's site-of-care office (if this is selected, please proceed to next section)

☐ Alternate site of care ☐ Hospital outpatient ☐ Other _____

Name of Institution/Practice Name _____ Physician or Infusion Provider Name _____

Provider's Specialty _____

Address _____ City _____ State _____ ZIP _____

Office Contact _____ Email _____

Office Phone (and Extension) _____ Office Fax _____ Site Tax ID _____

PHYSICIAN/OFFICE INFORMATION

Prescriber's Name (Print) _____ Practice/Group Name _____

Address _____ Suite _____

City _____ State _____ ZIP _____

Office Contact Person _____

Office Phone _____ Office Fax _____

License # _____ NPI # _____

Preferred Medical Facility (Name, Phone #) _____

List of Facilities Where Physician Has Privileges _____

By signing below, I certify that I am the prescribing provider mentioned above, that I am part of the Chiesi Total Care Program, that the therapy described above is medically necessary, and that all the medical necessity information is true, accurate, and complete. The patient's records contain supporting documentation that substantiates the utilization and medical necessity of the products marked above. I provide permission to use my personal information and the personal information of the patient provided above to facilitate this request and complete any regulatory or legal requirements associated with this request. I understand that the personal information provided herein may be shared with Chiesi, successors, and their agents and service providers as needed to support this request. I also attest that I have obtained the patient's authorization to release the above information and such other personal information as may be necessary for the Chiesi Total Care Program and/or their agents and service providers. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian. If my patient is eligible for free product, I understand that receiving free product is not contingent on any purchase obligations. I also understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; nor may I bill any payer for administration of such product. I understand that any falsification, omission, or concealment of material fact may result in criminal liability.

Prescriber's Signature _____ _____ Date _____

Substitution Permitted Dispense as Written

Questions? Chiesi Total Care is here to help! Please contact Chiesi Total Care at 1-855-282-4883 if you have questions regarding this form.
Please see Important Safety Information for Lamzede, including Boxed Warning, below.

Indication

Lamzede® (velmanase alfa-tycv) is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

Important Safety Information

WARNING: SEVERE HYPERSENSITIVITY REACTIONS

Hypersensitivity Reactions Including Anaphylaxis

Patients treated with Lamzede have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Lamzede administration. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue Lamzede immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Lamzede may be considered.

Considerations Due to Hypersensitivity Reactions and/or Infusion-Associated Reactions (IARs)

Prior to Lamzede administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and IARs and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Lamzede administration and initiate appropriate medical treatment.
- In the event of a mild to moderate hypersensitivity reaction or a mild to moderate IAR, consider temporarily holding the infusion for 15 to 30 minutes, slowing the infusion rate to 25% to 50% of the recommended rate, and initiating appropriate medical treatment.

Hypersensitivity Reactions Including Anaphylaxis

Anaphylaxis and severe hypersensitivity signs and symptoms included cyanosis, hypotension, emesis, urticaria, erythema, facial swelling, pyrexia, and tremor.

Infusion-Associated Reactions (IARs)

The most frequent symptoms of IARs that occurred in >10% of the population were pyrexia, chills, erythema, vomiting, cough, urticaria, rash, and conjunctivitis.

Females of Reproductive Potential

Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede is discontinued. For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment with Lamzede.

Embryo-Fetal Toxicity

Based on findings from animal reproduction studies, Lamzede may cause embryo-fetal harm when administered to a pregnant female.

Common Adverse Reactions

The most common adverse reactions (incidence >20%) are hypersensitivity reactions including anaphylaxis, nasopharyngitis, pyrexia, headache, and arthralgia.

Please see Full Prescribing Information for Lamzede.

For more information, visit Lamzede.com.

PP-VA-0150 V1.0

Lamzede®
velmanase alfa-tycv