Lamzede Home Infusion Nursing Order Form

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

PATIENT INFORMATION

Patient Name (Last, First) _____

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

Address _____ City _____ State _____ ZIP _____

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

MEDICAL INFORMATION

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

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

Prior Therapies _____

Current Medications _____

History of Infusion-Related Reactions _____

LAMZEDE® (VELMANASE ALFA-TYCV) 1 SINGLE-USE 10-mg VIAL ORDER

Total Dose (mg) Per Infusion _____

Route of Administration IV _____

Frequency _____

Quantity (1-month supply) _____

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

Number of Refills _____

Infusion Rate (mL/hour) _____

The recommended dosage is 1 mg/kg (actual body weight) administered every week as an intravenous infusion.

NURSING ORDERS

Vital sign monitoring:

☐ Monitor vital signs at the start of the infusion, at the end of the infusion and observation period, and PRN _____

- Post-infusion observation
  - ☐ _____ minutes
  - ☐ No observation
- The recommended dose is 1 mg/kg of body weight for pediatric and adult patients
  - – Appropriate number of vials calculation (round up to next whole # if the # of calculated vials includes a fraction): = Patient dose (mg) ÷ 10 mg/vial (content of 1 vial)
  - – Infusion duration is calculated individually, with a maximum infusion rate of 25 mL/hour

- Intravenous access and flush orders (min of 10 mL post-infusion):
  - ☐ Peripheral IV line:
    - – Post-infusion: sodium chloride 0.9% _____
  - ☐ Implanted port/central line:
    - – Before infusion: 0.9% sodium chloride injection 5-10 mL
    - – After infusion: 0.9% sodium chloride injections 10 mL and heparin (100 units/mL) 5 mL

If a severe reaction occurs, immediately discontinue Lamzede, initiate appropriate medical treatment and contact the prescriber.

If a mild to moderate reaction occurs, consider slowing or temporarily withholding Lamzede, initiate appropriate medical treatment, and contact the prescriber.

PHYSICIAN/OFFICE INFORMATION

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

Address _____ Suite _____

City _____ State _____ ZIP _____

Office Contact Person _____ Office Phone _____

Emergency Cell Phone _____ Office Fax _____

License # _____ NPI # _____

Lamzede Home Infusion Nursing Order Form (cont'd)

MEDICATION ORDERS

Select pre-medication(s) needed for this administration:

Oral (PO) medications to be obtained and self-administered by patient

☐ EMLA™ Cream
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Methylprednisolone
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Acetaminophen
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Famotidine
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Diphenhydramine (50 mg/mL)
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Other: _____
Dose _____ Route _____
Physician Directions _____
Quantity _____ Refills _____

Additional orders:

Select PRN medications:

Oral (PO) medications to be obtained and self-administered by patient

☐ Methylprednisolone
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Acetaminophen
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Famotidine
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Diphenhydramine
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Albuterol sulfate inhalation aerosol for oral inhalation
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Epinephrine auto-injector
Dose _____
Physician Directions _____
Quantity _____ Refills _____

☐ Other: _____
Dose _____ Route _____
Physician Directions _____
Quantity _____ Refills _____

☐ Emergency kit:
- Epinephrine auto-injector
- PPE for administering CPR

MANDATORY OFFICE CHECKLIST

☑ Please confirm that you have completed each of the following steps:

☐ The patient has had successful infusions in an outpatient setting

☐ The patient is medically stable and safe for home infusion therapy

☐ The patient has been prescribed an epinephrine auto-injector

☐ The patient lives in an area where emergency medical services are available

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.

X _____

Treating Physician's Signature **Date**

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 accompanying Full Prescribing Information for Lamzede.