

# Chiesi Total Care<sup>SM</sup> Patient Support Services Program Terms and Conditions

These terms and conditions apply to the patient support services offered through the Chiesi Total Care Patient Support Program (the “Program”) for LAMZEDE, unless otherwise noted. These patient support service programs may include affordability solutions support, appeals support, benefit verification, Clinical Nurse support, copay assistance, patient assistance, Pharmacist support, and prior authorization support. Patient support services offered through the Program are subject to change.

A patient who receives health care benefits under any plan or program funded in whole or in part by federal or state governments including Medicare, Medicaid, TRICARE, Veterans Affairs (VA), State Prescription Assistance Plans (SPAPs) (other than health insurance for federal government employees) or any state health care program such as Medicaid, Children’s Health Insurance Program, programs funded under Maternal and Child Health Program or programs funded under Social Services Block Grant (collectively, “Government-funded Plans”) are not eligible for patient support services that provide financial support through the Program. A patient covered under a commercial health plan purchased through a health insurance marketplace or exchange is not a government program beneficiary even if the costs of such coverage are subsidized by the federal government. Only patients with commercial insurance who have a valid prescription for a US Food and Drug Administration-approved indication for LAMZEDE are eligible for patient support services that provide financial support through the Program.

To enroll in any of the patient support services of the Program, the patient must also enroll in Chiesi Total Care. The patient must be a resident of the US or one of its territories. If the Patient is incapable of acting on their own behalf or if the Patient is under 18 years old, enrollment into the Program may be completed by another person acting on their behalf (such as a caregiver).

If at any time a patient begins receiving prescription drug coverage under any Government-funded Plan, patient will no longer be able to participate in the patient support services programs that provide financial support through the Program and patient must notify the Program to stop participation.

Patients residing in or receiving treatment in certain states may not be eligible for the Lamzede Copay Assistance Program, the Infusion Services Program, or any Lamzede Routine Testing Program. Patients residing in or receiving treatment in Massachusetts, Michigan, Minnesota, or Rhode Island are not eligible for the Infusion Copay Assistance Program or the Lamzede Routine Testing Program. Patients may not seek reimbursement for value received from Copay Programs. The Copay Programs do not obligate the use of any specific medication or health care provider. Participation in a Copay Program is not conditioned on any past, present, or future purchase.

To determine financial eligibility for participation in the Patient Assistance Program, patient will be asked to provide the size of the household, annual household income, and proof of income. Proof of income may include W2 form(s), paycheck stubs, and/or prior year tax returns.

Program benefits may not be sold, purchased, traded, or offered for sale, purchase, or trade. The Chiesi Total Care patient support services are not valid where prohibited by law, taxed, or otherwise restricted. Offer subject to change or discontinuance without notice. Restrictions, including monthly maximums, may apply. This is not health insurance.

This is a voluntary program. Patients who choose not to enroll in any of the support programs will still be able to receive medication. Patients may participate in Chiesi Total Care without participating in a support program.

After enrolling in Chiesi Total Care, participants may opt out by contacting Chiesi Total Care, as outlined in the Chiesi Total Care Enrollment and Authorization Form. Patients must renew their eligibility by December 31 of each year to continue to receive support under the Program.

By participating in the Program, participants acknowledge that they understand and agree to comply with these Terms and Conditions.

## Indication

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

## Important Safety Information

### What is the most important information I should know about Lamzede?

**Severe allergic reactions (hypersensitivity reactions) including anaphylaxis, may occur during and after Lamzede treatment. If severe allergic reactions or anaphylaxis occur during treatment, your healthcare provider will immediately stop the infusion and provide appropriate medical care. If these reactions should occur after treatment, seek immediate medical care.**

### What should I know about infusions?

Your healthcare provider may give you other medications prior to your next infusion to help manage allergic reactions and infusion-related side effects. They will explain how to recognize the signs and symptoms of these allergic reactions and infusion-related side effects. If these signs and symptoms occur, it’s important for you to seek immediate medical care.

### What are the common signs and symptoms of an allergic reaction or infusion-related side effects with Lamzede?

In clinical trials, some patients experienced signs and symptoms of an allergic reaction, which included bluish skin discoloration, low blood pressure, vomiting, hives, skin redness, facial swelling, fever, and involuntary movements.

In clinical trials, when patients experienced an infusion-related side effect, the most common signs were fever, chills, skin redness, vomiting, cough, itching, rash, and pink eye.

### Are there certain people who should or should not take Lamzede?

Lamzede may cause harm to your unborn baby. For females who are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with Lamzede. Tell your healthcare provider right away if you become pregnant or think you may be pregnant. You should use effective birth control during treatment with Lamzede and for at least 14 days after the last dose.

### What are the most common side effects of Lamzede?

Lamzede can cause side effects including severe allergic reactions and anaphylaxis, common cold, fever, headache, and joint pain or stiffness.

### Please see [Full Prescribing Information](#) for Lamzede.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.