

Chiesi Total CareSM Patient Support 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 Elfabrio, 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 healthcare 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 healthcare 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 (FDA)-approved indication for Elfabrio 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 the patient begins receiving prescription drug coverage under any Government-funded Plan, the patient will no longer be able to participate in the patient support service programs that provide financial support through the Program, including, but not limited to, any Copay Assistance Program, Elfabrio Testing Program, or Elfabrio Home Infusion Program.

Patients residing in or receiving treatment in Massachusetts, Michigan, Minnesota, or Rhode Island are not eligible for the Elfabrio Home Infusion Program, Home Infusion Copay Assistance Program, or any Elfabrio Testing Program. Patients may not seek reimbursement for value received from the Copay Programs. The Copay Programs do not obligate the use of any specific medication or healthcare 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, the 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

Elfabrio[®] (pegunigalsidase alfa-iwxj) is a prescription infusion medicine used to treat adults with confirmed Fabry disease.

Important Safety Information

What is the most important information I should know about Elfabrio?

Severe allergic reactions (hypersensitivity reactions), including anaphylaxis, may occur during and after Elfabrio treatment. If severe allergic reactions or anaphylaxis occurs 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 Elfabrio infusions?

Your healthcare provider may give you other medications prior to your Elfabrio infusions 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. If the reaction is mild to moderate, your healthcare provider may choose to slow the infusion rate or withhold the dose.

In clinical trials, 41 patients (29%) experienced an infusion-related side effect. The most common signs and symptoms of an infusion-related reaction with Elfabrio were hypersensitivity, nausea, chills, itchy skin, rash, chest pain, dizziness, vomiting, feelings of weakness, pain, sneezing, shortness of breath, nasal congestion, throat irritation, abdominal pain, skin redness, diarrhea, burning sensation, nerve pain, headache, tingling or numbness, shaking movements, agitation, increased body temperature, flushing, slow heart rate, muscle pain, high blood pressure, and low blood pressure.

Your healthcare provider will do blood and urine tests to check your kidney function during treatment with Elfabrio.

The most common side effects of Elfabrio include infusion-related side effects, common cold, headache, diarrhea, fatigue, nausea, back pain, pain in the limbs, and sinus infection.

Please see **Full Prescribing Information** for Elfabrio.

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



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PP-EF-0130 V2.0

