Chiesi TOTAL care℠

Prior Authorization and Access Guide

Visit chiesitotalcare.com or call 1-833-656-1056—we're ready to help!

Indication

Elfabrio® (pegunigalsidase alfa-iwxj) is indicated for the treatment of adults with confirmed Fabry disease.

Important Safety Information

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

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

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning, in pocket.

ELFABRIO®
(pegunigalsidase alfa-iwxj)

Chiesi Total Care℠ will submit for insurance reimbursement and help you navigate prior authorization (PA)

HERE'S A STEP-BY-STEP LOOK AT THE PROCESS

1 SUBMISSION

The Chiesi Total Care Team starts the process when a new Rx form is submitted.

The Chiesi Total Care Team helps you submit PA.

2 MONITORING PA

Chiesi Total Care monitors and tracks PA submission until an outcome is determined by the payer.

PA IS APPROVED

- Your office and/or patient is notified

PA IS DENIED

- Send denial documentation to Chiesi Total Care
- Chiesi Total Care can help in denial situations with a high success rate

3 APPEAL

Based on the letter, Chiesi Total Care can submit a patient-level appeal with signed patient consent.

OR

Your office can submit a physician-level appeal. Chiesi Total Care can assist and coach on best practices.*

*Chiesi Total Care assistance is neither medical guidance nor a suggestion that you submit an appeal. The resources and information provided in this guide are general in nature and are not intended to be conclusive or exhaustive. As the patient's healthcare provider, you are responsible for applying your clinical judgment regarding their appropriate care and treatment.

4 PA OR APPEAL IS APPROVED

The pharmacy fills the Rx and medication is dispensed to the patient.

Contact your dedicated Chiesi Total Care Program Specialist with any questions you may have about your case.

PA denied? Chiesi Total Care is here to help

It's not uncommon for the first PA submission to be denied. With a long track record of success in gaining PA and appeal approvals, Chiesi Total Care is here to provide assistance with the appeal process. Chiesi Total Care will assist in providing additional resources and/or publications depending on the reasons for denial. To request a copy of an additional resource or publication, please reach out directly to **us.medical@chiesi.com**.

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Chiesi TOTAL care℠

We provide updates on your patient's therapy and alert the office should there be an issue with compliance. We also help patients stay compliant by helping them cope with side effects and answering questions.

We can help by:

- Alerting when to refill or when refills are being missed
- Counseling patients on managing side effects
- Providing 24/7 pharmacist access
- Enrolling patients in one or both of the Elfabrio Copay Programs—eligible patients may pay as little as $0 for their prescription and/or Elfabrio infusion supplies and administration†

Lesa, Chiesi Total Care pharmacist

†Government-funded plans are not eligible for patient support services that provide financial support through the programs. Patients receiving treatment or residing in MA or RI are not eligible for home infusion services. To receive home infusion support, patients must be referred to home infusion by their prescribing physician.

Best practices for PA submission:

- ☐ Include clinical notes, dates, and laboratory findings
- ☐ Include the prescribing physician's NPI number and contact information
- ☐ Include medical rationale for why the patient cannot use preferred formulary drugs
- ☐ Include documentation of alternative therapeutic treatments that were tried, failed, inadequate, or contraindicated

NPI, National Provider Identifier.

Important Safety Information (continued)

Prior to Elfabrio administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and infusion-associated reactions (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 Elfabrio administration and initiate appropriate medical treatment.
- If a mild to moderate hypersensitivity reaction or IAR occurs, consider slowing the infusion rate or temporarily withholding the dose.

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Important Safety Information (continued)

In clinical trials, 20 (14%) Elfabrio-treated patients experienced hypersensitivity reactions. Four Elfabrio-treated patients (3%) experienced anaphylaxis reactions that occurred within 5 to 40 minutes of the start of the initial infusion. The signs and symptoms of hypersensitivity reactions and anaphylaxis included headache, nausea, vomiting, throat tightness, facial and oral edema, truncal rash, tachycardia, hypotension, rigors, urticaria, intense pruritus, moderate upper airway obstructions, macroglossia, and mild lip edema.

In clinical trials, 41 (29%) Elfabrio-treated patients experienced one or more infusion-associated reactions, including hypersensitivity, nausea, chills, pruritus, rash, chest pain, dizziness, vomiting, asthenia, pain, sneezing, dyspnea, nasal congestion, throat irritation, abdominal pain, erythema, diarrhea, burning sensation, neuralgia, headache, paresthesia, tremor, agitation, increased body temperature, flushing, bradycardia, myalgia, hypertension, and hypotension.

A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trials. Monitor serum creatinine and urinary protein-to-creatinine ratio. If glomerulonephritis is suspected, discontinue treatment until a diagnostic evaluation can be conducted.

When switching to Elfabrio from a prior enzyme replacement therapy, the risk of hypersensitivity reactions and infusion-associated reactions may be increased in certain patients with pre-existing anti-drug antibodies (ADAs). Consider monitoring IgG and IgE ADAs and clinical or pharmacodynamic response (eg, plasma lyso-Gb3 levels).

The most common adverse reactions (≥15%) were infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

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For more information, visit elfabrio.com.
Chiesi Total Care℠ is offered through EVERSANA® Life Science Services Specialty Pharmacy.

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