Chiesi Total Care℠ Fact Sheet

ELFABRIO® (pegunigalsidase alfa-iwxj)

A single call to your dedicated Chiesi Total Care Team is all it takes—we will guide you through the process of getting a patient started on Elfabrio® (pegunigalsidase alfa-iwxj) therapy.

Insurance eligibility—Chiesi Total Care assists you and your patients with:

Commercial insurance

If your patients have private insurance through their job or their own business

Government insurance

If your patients have Medicare, Medicaid, Veterans Affairs healthcare, or other government insurance

No insurance

If your patients have no insurance, they may be eligible for financial assistance

Copay Assistance

Chiesi Total Care offers 2 copay programs for eligible patients*:

Prescription copay: This covers the medication itself. Patients may pay as little as $0 for their Elfabrio prescription

Infusion assistance copay: This covers infusion supplies and administration (including home infusion). Patients may pay as little as $0 for these expenses

To be eligible for these programs:

- Your patient must be enrolled in Chiesi Total Care. (Enrollment and Authorization Form will be mailed to your patient's home)
- Your patient must have commercial insurance and a valid prescription for a US Food and Drug Administration (FDA)-approved indication for Elfabrio
- Your patient must be a resident of the United States or one of its territories

Please refer to the accompanying full Terms and Conditions for additional eligibility requirements.

*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.

The dedicated Chiesi Total Care Team is made up of:

Pharmacists | Patient Service Coordinators | Reimbursement support | Nursing support

Additional Offerings

Infusion assistance†

- Chiesi Total Care may help patients understand their medication and the infusion process, and coordinate a suitable infusion site if needed
- If you determine home infusion is right for your patient, Chiesi Total Care may be able to assist eligible patients with delivery of medication and infusion supplies needed

†Patients receiving treatment or residing in MA or RI are not eligible for infusion assistance. To receive home infusion support, patients must be referred to home infusion by their prescribing physician. Please see the accompanying full Terms and Conditions for additional eligibility requirements.

Routine testing

- Healthcare providers should consider monitoring for the presence of IgG and IgE antibodies in patients who demonstrate hypersensitivity reactions and should consider the risks and benefits of continued treatment in patients with anti-Elfabrio IgG and IgE antibodies. There are no marketed tests for these antibodies against Elfabrio. If monitoring is warranted, Chiesi Total Care may be able to help

IgE, immunoglobulin E; IgG, immunoglobulin G.

Important Safety Information

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

Please see complete Important Safety Information for Elfabrio, including Boxed Warning concerning hypersensitivity reactions including anaphylaxis, on back, and accompanying Full Prescribing Information.

Phone
1-833-656-1056

Chiesi Total Care℠

Scan the QR code for the Enrollment Form

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.

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.

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.

Please see accompanying Full Prescribing Information for Elfabrio and full Terms and Conditions for additional Chiesi Total Care eligibility requirements.

Contact Information

Phone
1-833-656-1056

Website
chiesitotalcare.com

Chiesi global rare diseases

PP-EF-0464 V1.0

Chiesi TOTAL care℠ | ELFABRIO® (pegunigalsidase alfa-iwxj)