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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	June 2, 2023
Subject:	Elfabrio	**Page:**	1 of 3

Last Review Date: March 8, 2024

Elfabrio

Description

Elfabrio (pegunigalsidase alfa-iwxj)

Background
Fabry disease is caused by deficiency of the lysosomal enzyme alpha-galactosidase A. Clinical manifestations of Fabry disease include neuropathy, renal failure, cardiomyopathy, and cerebrovascular accidents. Elfabrio provides an exogenous source of alpha-galactosidase A. Elfabrio is internalized and transported into lysosomes where it is thought to exert enzymatic activity and reduce accumulated globotriaosylceramide (Gb3) (1).

Regulatory Status
FDA-approved indication: Elfabrio is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease (1).

Elfabrio has a boxed warning regarding hypersensitivity reactions, including anaphylaxis. Prior to Elfabrio administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. If severe allergic or anaphylactic reactions occur, immediately discontinue Elfabrio and initiate appropriate medical treatment (1).

Infusion-associated reactions have been reported in Elfabrio-treated patients. Patients with advanced Fabry disease may have compromised cardiac function, which may predispose them to a higher risk of severe complications from infusion reactions. Appropriate medical support measures should be readily available when Elfabrio is administered because of the potential for severe infusion reactions (1).

The safety and effectiveness of Elfabrio in pediatric patients less than 18 years of age have not been established (1).

Related policies
Fabrazyme, Galafold

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Elfabrio may be considered **medically necessary** if the conditions indicated below are met.

Elfabrio may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Fabry disease

AND the following:

1. Prescriber agrees to monitor the patient for hypersensitivity reactions, including anaphylaxis, during Elfabrio administration

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 2 years

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Elfabrio is indicated for use in patients with Fabry disease. Elfabrio provides an exogenous source of alpha-galactosidase A and reduces accumulated Gb3. Life-threatening anaphylactic and severe allergic reactions have been observed in some patients during Elfabrio infusions. The safety and effectiveness of Elfabrio in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Elfabrio while maintaining optimal therapeutic outcomes.

References

1. Elfabrio [package insert]. Cary, NC: Chiesi USA, Inc.; May 2023.

Policy History

Date	Action
June 2023	Addition to PA
September 2023	Annual review. Per SME, added clinical manifestations of Fabry disease including neuropathy to background section
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.