pegunigalsidase alfa-iwxj (Elfabrio)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration
Outpatient Facility Administration
Infusion Center Administration
Home Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Enzyme replacement therapy
HCPCS:
J2508:Injection, pegunigalsidase alfa-iwxj, 1 mg
How Supplied:
NDCs:
10122-160-02: 20 mg/10 mL (2 mg/mL) 1 single-dose vial
10122-160-05: 20 mg/10 mL (2 mg/mL) 5 single-dose vials
10122-160-10: 20 mg/10 mL (2 mg/mL) 10 single-dose vials

Condition(s) listed in policy *(see coverage criteria for details)*

- Fabry Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.
For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF ELFABRIO IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is initiating therapy (allowed for the first 6 months) with Elfabrio or is being re-initiated on Elfabrio after at least 6 months off therapy.** *Subsequent doses after the first 6 months will require medical necessity for continued use in the hospital outpatient facility site of care.*

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on Elfabrio based on documentation submitted.**
3. **Patient continues to experience moderate to severe adverse events on Elfabrio based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**
4. **Patient is clinically unstable based on documentation submitted.**
5. **Patient is physically or cognitively unstable based on documentation submitted.**

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Fabry Disease

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication
2. Presence of the galactosidase alpha (GLA) gene mutation
3. Not being used in combination with migalastat (Galafold)

Covered Doses:

Up to 1 mg/kg given as an intravenous infusion every 2 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

E75.21

References

1. AHFS®. Available by subscription at http://www.lexi.com
2. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Elfabrio (pegunigalsidase alfa) [prescribing information]. Cary, NC: Chiesi USA; May 2023.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee