pegunigalsidase alfa-iwxj (Elfabrio)

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 Disorder
Mechanism of Action: Enzyme replacement therapy
HCPCS:

- Effective through 12/30/2023: C9399, J3490, J3590
- Effective 1/1/2024 and after: J2508 per 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

Special Instructions and pertinent Information

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

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****
AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

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

1. Patient is ≥ 18 years of age, AND
2. Presence of the galactosidase alpha (GLA) gene mutation, AND
3. Not being used in combination with migalastat (Galafold)

Covered Doses
1 mg/kg given by IV infusion every 2 weeks

Coverage Period
Indefinite

Additional Information:

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-iwxj). [Prescribing information]. Cary, NC: Chiesi USA, Inc.; 5/2023.

Policy Update

Date of Last Annual Review: New policy
Date of last revision: 1/3/2024
Changes from previous policy version:

- Added HCPCS J2508 per 1 mg, effective 1/1/2024 and after.

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