blue california
Promise Health Plan

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.

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