

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 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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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*