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 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
10122-165-02: 5mg/2.5ml (2mg/ml) 1 single-dose vial

## 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)



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**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 2024.


## Review History

Date of Last Annual Review: 2Q2026
Changes from previous policy version:

- No change to policy following routine annual review

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