blue california
Promise Health Plan

agalsidase beta (Fabrazyme)

Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: Biosynthetic (recombinant DNA origin) form of human alpha-galactosidase.

How Supplied:
5 mg or 35 mg (single-use)

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. Patient has galactosidase-alpha (GLA) gene mutation
2. Patient is 2 years of age and older
3. Not being used with migalastat (Galafold)

Covered Doses:
Up to 1 mg/kg given intravenoulsy every 2 weeks

Coverage Period:
Indefinite

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. Fabrazyme (agalsidase beta) Prescribing Information. Genzyme, Inc., Cambridge, MA: 7/2024.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change to policy following annual review.

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