

agalsidase beta (Fabrazyme)

Commercial 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.

HCPCS:

J0180:Injection, agalsidase beta, 1 mg

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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** 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.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG 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 2 doses) with Fabrazyme or is being re-initiated on Fabrazyme after at least 6 months off therapy. *Subsequent doses 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 Fabrazyme based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Fabrazyme 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

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 intravenously 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:

agalsidase beta (Fabrazyme)

- No clinical change to policy following annual review.

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