Agalsidase beta (Fabrazyme®)

Place of Service

Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Administration*
[***Prior authorization required – see section (1)]

HCPCS: J0180 per 1 mg

Condition listed in policy (*see criteria for details*)

- Fabry disease

AHFS therapeutic class: Enzymes

Mechanism of action: Biosynthetic (recombinant DNA origin) form of human αlpha-galactosidase.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

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

ADMINISTRATION OF FABRAZYME 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 infusions) 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)
All requests for Fabrazyme® (agalsidase beta) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Fabry disease

1. Provider attestation that patient has galactosidase-alpha (GLA) gene mutation, **AND**
2. Patient is 2 years of age and older, **AND**
3. Not being used with migalastat (Galafold)

Covered Doses
Up to 1 mg/kg IV infusion every 2 weeks

Coverage Period
Indefinite

ICD-10:
E75.21

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Fabrazyme® (agalsidase beta) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied: 5 mg or 35 mg (single-use vials)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Fabrazyme (agalsidase beta) [Prescribing information]. Cambridge, MA.: Genzyme, Inc.; March 2021.
- Laney DA, Bennett RL, Clarke V, et al. Fabry Disease Practice Guidelines: Recommendations of the National Society of Genetic Counselors. *J Genet Counsel.* 2013;22:555-564.
- Michael Mauer MD, Jeffrey Kopp MD. UpToDate. Fabry disease: Clinical features and diagnosis. June 10, 2020.

(7) Policy Update
Date of last review: 2Q2023
Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee