Fabrazyme (agalsidase)

Effective Date: January 1, 2021	Number: MG.MM.PH.311

Definitions

Fabrazyme is human α-galactosidase A (α-Gal), with the same amino acid sequence as the native enzyme. It is produced in Chinese hamster ovary cells via recombinant DNA technology. Fabrazyme catalyzes the breakdown of globotriaosylceramide (GL-3) and other α-galactyl-terminated neutral glycosphingolipids to ceramide and galactose. Fabrazyme is indicated for use in patients with Fabry disease. It reduces the deposition of GL-3 in the capillary endothelium of the kidney and certain other cell types.

Dosing

Each dose must not exceed 1 mg/kg administered intravenously no more frequently than once every 2 weeks.

Length of Coverage

- Approvals will be granted for 12 months

Guideline

Fabry Disease

- The diagnosis is established by **one** of the following:

  - Patient has a laboratory test demonstrating deficient α-galactosidase A activity in leukocytes or fibroblasts; **OR**
  - Patient has a molecular genetic test demonstrating mutations in the galactosidase alpha gene; **AND**
- Fabrazyme is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

Limitations/Exclusions

- Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

Applicable Procedure Codes

J0180	Injection, agalsidase beta, 1 mg; 1 billable unit = 1 mg

Applicable Procedure Codes

54868-0041-xx	Fabrazyme 5 mg single-use vial for injection
54868-0040-xx	Fabrazyme 35 mg single-use vial for injection

Applicable Diagnosis Codes

E75.21	Fabry (-Anderson) disease

Revisions

1/1/2021	Criteria apply to Commercial, Medicare, and Medicaid members.

REFERENCES

1. Fabrazyme® injection [prescribing information]. Cambridge, MA: Genzyme Corporation; December 2018.
2. Schiffmann R. Fabry Disease. *Handb Clin Neurol*. 2015;132:231-248.
3. Arends M, Wanner C, Hughes D, et al. Characterization of Classical and Nonclassical Fabry Disease: A Multinational Study. *J Am Soc Nephrol*. 2017;28:1631-1641.
4. 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.