

Fabrazyme® (agalsidase beta)

When requesting Fabrazyme® (agalsidase beta), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Fabrazyme (agalsidase beta) is indicated for the treatment of individuals with Fabry disease.

Coverage Guidelines

Fabry Disease

The individual must meet all of the following criteria for approval:

- Diagnosis is confirmed by one of the following:
 - o Laboratory test demonstrating deficient α -galactosidase A activity in leukocytes or fibroblasts; OR
 - o Molecular genetic test demonstrating a pathogenic variant in the galactosidase alpha gene;
- Fabrazyme is prescribed by or in consultation with a geneticist, an endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

Approval duration: 12 months

Dosing Recommendation

The recommended dosage of Fabrazyme is 1 mg/kg (actual body weight) administered by intravenous infusion every 2 weeks.

References

1. Fabrazyme® injection [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2023.
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.