Mass General Brigham
Health Plan

Fabrazyme (agalsidase beta)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Fabrazyme (agalsidase beta) is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of confirmed Fabry disease in adults and pediatric patients at least 2 years of age.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

1. Member meets ONE of the following:
    a. The member is diagnosed with Fabry disease as confirmed by enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing: Documentation is required
    b. The member is a symptomatic obligate carrier: Documentation is required
2. The member will not use Fabrazyme in combination with Galafold or Elfabrio
3. The prescriber is a nephrologist, cardiologist or a specialist in metabolic disorders or genetics

<u>Continuation of Therapy</u>
Requests for reauthorization will be approved when the following criteria are met:

1. Documentation (e.g., medical charts/lab results) is submitted demonstrating that the member is responding to therapy (e.g., reduction in plasma globotriaosylceramide [GL-3] or GL-3 inclusions, improvement and/or stabilization in renal function, pain reduction)

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months

References

1. Fabrazyme (agalsidase beta) [prescribing information]. Cambridge, MA: Genzyme Corporation; July 2024.
2. Galafold (migalastat) [prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; October 2024.
3. Germain DP, Arad M, Burlina A, et al. The effect of enzyme replacement therapy on clinical outcomes in female patients with Fabry disease - A systematic literature review by a European panel of experts. Mol Genet Metab 2019; 126:224
4. Ortiz A, Germain DP, Desnick RJ et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018; 123(4):416-427
5. Ramaswami U, Bichet DG, Clarke LA, et al. Low-dose agalsidase beta treatment in male pediatric patients with Fabry disease: A 5-year randomized controlled trial. Mol Genet Metab 2019; 127:86
6. Schiffmann R, Pastores GM, Lien YH, et al. Agalsidase alfa in pediatric patients with Fabry disease: a 6.5-year open-label follow-up study. Orphanet J Rare Dis 2014; 9:169

Review History

09/22/2021- Administrative change to custom template; added prescriber is a specialist. Effective 02/01/2022.
09/21/2022 – Reviewed at Sept P&T; no changes.
12/11/2024 – Reviewed at December P&T. Updated initial criteria to require that member will not use Fabrazyme in combination with Elfabrio. Updated reauthorization criteria to include additional examples of positive response and clarified that documentation requires medical charts or lab results. Effective 03/01/2025.