

**Fabrazyme (agalsidase beta)
Effective 02/01/2022**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Fabrazyme 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 who are currently receiving treatment with Fabrazyme 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, and documentation is provided:

1. ONE of the following is met:
 - 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.
3. The prescriber is a nephrologist, cardiologist or a specialist in metabolic disorders or genetics

Continuation of Therapy

Reauthorization requires physician documentation which shows the member is responding to therapy (e.g., reduction in plasma globotriaosylceramide [GL-3] or GL-3 inclusions)

Limitations

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



References

1. Fabrazyme (agalsidase beta) [package insert]. Cambridge, MA: Genzyme Corporation; March 2021.
2. Galafold (migalastat) [prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; February 2021
3. 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
4. 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
5. 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
6. 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

Review History

09/22/2021- Administrative change to custom template; added prescriber is a specialist. Effective 02/01/2022.

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