Clinical Policy Title:	migalastat
Policy Number:	RxA.149
Drug(s) Applied:	Galafold®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Fabry Disease (must meet all)**:**

1. Diagnosis of Fabry disease confirmed by one of the following (a or b):
   a. Enzyme assay demonstrating a deficiency of alpha-galactosidase activity;
   b. DNA testing;
2. Presence of at least one amenable GLA variant (mutation), as confirmed by one of the following resources (a, b, or c):
   a. Galafold® Prescribing Information brochure (package insert; Section 12, Table 2);
   b. Amicus Fabry GLA Gene Variant Search Tool: http://www.galafoldamenabilitytable.com/hcp;
   c. Amicus Medical Information at 1-877-4AMICUS or medinfousa@amicusrx.com;
3. Galafold® is not prescribed concurrently with Fabrazyme®.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Fabry Disease (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Hopkin RJ, Jefferies JL, Laney DA, et al. on behalf of the Fabry Pediatric Expert Panel. The management and treatment of children with Fabry disease: A United States-based perspective. Molecular Genetics and Metabolism. February 2016; 117(2): 104-113. Available at: https://doi.org/10.1016/j.ymgme.2015.10.007. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	1/2020	02/07/2020
Policy was reviewed: 1. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been	06/15/2020	09/14/2020

authorized by RxAdvance..." 2. References reviewed and updated.		
Policy was reviewed: 1. Continued therapy approval criteria II.A.1 was updated to "Member is currently receiving medication…". 2. References updated.	03/31/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.2 was updated to add nephrologist, or a physician who specializes in the treatment of Fabry disease. 2. References were reviewed and updated.	01/10/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of Fabry disease to Diagnosis of Fabry disease confirmed by one of the following (a or b): a. Enzyme assay demonstrating a deficiency of alpha-galactosidase activity; b. DNA testing. 2. Initial Approval Criteria, I.A.2: Updated prescriber criteria from Prescribed by or in consultation with a clinical geneticist, nephrologist or a physician who specializes in the treatment of Fabry disease to Prescribed by or in consultation with a clinical geneticist, cardiologist, nephrologist, neurologist, or a physician who specializes in the treatment of Fabry disease. 3. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024