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
2. Galafold (migalastat) [prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; February 2021

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

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.