Galafold (migalastat)
Effective 12/1/2019

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Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

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<th>Non-Specialty Medications</th>
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<td></td>
<td>All Plans Phone: 866-814-5506 Fax: 866-249-6155</td>
<td>MassHealth Phone: 877-433-7643 Fax: 866-255-7569</td>
<td>All Plans Phone: 844-345-2803 Fax: 844-851-0882</td>
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<tr>
<td></td>
<td>Commercial Phone: 800-294-5979 Fax: 888-836-0730</td>
<td>Exchange Phone: 855-582-2022 Fax: 855-245-2134</td>
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Exceptions
N/A

Overview
Migalastat is FDA indicated for Fabry disease. It is an oral pharmacological chaperone that stabilizes certain mutant variants of alpha-galactosidase to increase enzyme trafficking to lysosomes. Migalastat reversibly binds to the active site of the alpha-galactosidase A (alpha-Gal A) protein (encoded by the galactosidase alpha gene, GLA), which is deficient in Fabry disease. Binding to the active site stabilizes alpha-Gal A allowing trafficking from the endoplasmic reticulum into the site of action, the lysosome.

Coverage Guidelines
Authorizations will be granted for members who are currently receiving treatment with Galafold, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs OR
Authorizations will be granted if the member meets all the following criteria and documentation has been submitted:
1. The member is at least 18 years of age
2. The member is diagnosed with Fabry disease
3. The prescriber is a clinical genetics specialist or nephrologist or consult with either specialist is provided
4. Results for enzyme assay test showing reduced or absent α-galactosidase A (α-GAL) enzyme activity in plasma, leukocytes, tears, or biopsied tissue are submitted
5. The member has GLA mutations which are amenable to treatment with Galafold

Limitations
1. Approvals will be granted for 12 months
2. Galafold will not be authorized in combination with enzyme replacement therapy (ERP)
References
1. Galafold (migalastat) [prescribing information]. Cranbury, NJ: Amicus Therapeutics US, Inc; June 2019

Review History
09/18/19 – Reviewed

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