Effective Date: 3/1/2021
Reviewed: 12/2020, 06/2021, 04/2022, 04/2023, 05/2024, 5/2025 Scope: Medicaid

GALAFOLD (migalastat)

POLICY

I. CRITERIA FOR INITIAL APPROVAL

Fabry disease with an amenable galactosidase alpha gene (*GLA*) variant
Authorization of 6 months may be granted for treatment of Fabry disease with documentation of an amenable galactosidase alpha gene (*GLA*) variant when all of the following criteria are met:

A. Patient is 18 years old or older; AND
B. The diagnosis of Fabry disease was confirmed (documentation provided) by enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, or the member is a symptomatic obligate carrier; AND
C. Documentation that the patient has an amenable galactosidase alpha gene *(GLA)* variant based on in vitro assay data; AND
D. Galafold will not be used in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj); AND
E. Documentation that the patient does not have severe renal impairment or end-stage renal disease requiring dialysis.

II. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in patients requesting reauthorization for Fabry disease with documentation of an amenable galactosidase alpha gene (*GLA*) variant who are responding to therapy (e.g., reduction in plasma globotriaosylceramide [GL-3] or GL-3 inclusions).

III. Quantity Limit

- 14 capsules per 28 days

IV. Coverage Duration

- Initial Approval: 6 months
- Continuation Approval: 6 months

V. REFERENCES

1. Galafold [package insert]. Philadelphia, PA: Amicus Therapeutics US, LLC; March 2025. Accessed May 2025.