

Galafold (migalastat)

Initial Coverage Criteria:

- 1. Prescribed by a specialist; and,
- 2. Prescribed for the treatment of Fabry disease; and,
- 3. Patient is ≥ 18 years of age; and,
- 4. Attestation by prescriber that the patient has a galactosidase alpha gene (GLA) variant that is amenable to Galafold therapy; and,
- 5. Patient is not currently on dialysis and has an eGFR ≥ 30 ml/min documented in clinic notes in the past 30 days; and,
- 6. For patients currently on Fabrazyme therapy the prescriber attests that Fabrazyme treatment will be discontinued upon initiation of Galafold therapy; and,
- 7. Prescribed within FDA approved dosing regimen.

Required Medical Information:

1. GFR documented in medical record within the past 30 days.

Reauthorization Criteria:

- 1. Patient continues to meet criteria above; and,
- 2. Patient has been seen and evaluated by the prescriber in the past 12 months; and,
- 3. Patient has been adherent to therapy.

Coverage Duration:

Initial authorizations will be provided for 6 months Reauthorization will be provided for 12 months

Other Criteria:

Maximum of 15 tablets per 30 days

P&T Date: 11/5/18

Effective Date: 2/1/19, Updated 11/10/2022