curative

Galafold Prior Authorization

Drug(s) Applied:	**Galafold** (migalastat)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Fabry disease** as indicated by chart notes within past 180 days
  1. Diagnosis was confirmed by mutation in the galactosidase alpha (GLA) gene **and**
  2. Patient has a confirmed amenable GLA variant based on in vitro assay data (a complete list of amenable variants is available in the Galafold prescribing information, or a specific variant can be verified as amenable at http://www.galafoldamenabilitytable.us/reference) **and**
  3. Patient's age is 18 years old or older **and**
  4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology, genetics, nephrology) **and**
  5. Chart notes and/or prescriber do not provide documentation of concurrent use with enzyme replacement therapy (ERT) (e.g., Fabrazyme, Elfabrio) for the requested indication.

Approval Duration: 6 months

II. Continued Therapy Criteria
- **A. Fabry disease** as indicated by chart notes within past 12 months
  1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
  2. Chart notes and/or prescriber do not provide documentation of concurrent use with enzyme replacement therapy (ERT) (e.g., Fabrazyme, Elfabrio) for the requested indication.

Approval Duration: 12 months

Policy Owned by: Curative PBM team