UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Galafold

Program	Prior Authorization
Medications	Galafold™ (migalastat)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New Mexico, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2018
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Galafold™ (migalastat) is an alpha-galactosidase A (alpha-Gal A) pharmacological chaperone indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on in vitro assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2. Coverage Criteria:

A. Initial Authorization

1. **Galafold** will be approved based on **all** of the following criteria:

   a. Diagnosis of Fabry disease

   -AND-

   b. Patient has an amenable galactosidase alpha gene (*GLA*) variant based on in vitro assay data

   -AND-

   c. Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

   Authorization will be issued for 12 months.

B. Reauthorization

1. **Galafold** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response to Galafold therapy

-AND-

b. Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Galafold [package insert]. Cranbury, NJ: Amicus Therapeutics, Inc.; March 2020.

Program	Prior Authorization – Galafold (migalastat)
Change Control	
9/2018	New program.
10/2019	Annual review. Updated reference.
10/2020	Annual review. No change to clinical coverage criteria. Added Additional Clinical Rules section. Reference updated.