UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1258-7
Program	Prior Authorization/Notification
Medications	Galafold® (migalastat)
P&T Approval Date	9/2018, 10/2019, 10/2020, 10/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

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]:

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) or Elfabrio (pegunigalsidase alfa-iwxj)

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) or Elfabrio (pegunigalsidase alfa-iwxj)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- 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]. Philadelphia, PA: Amicus Therapeutics US, LLC; June 2024.

Program	Prior Authorization/Notification – Galafold (migalastat)
Change Control	
9/2018	New program.
10/2019	Annual review with no changes to clinical coverage criteria. Updated reference.
10/2020	Annual review. No change to clinical coverage criteria. Reauthorization changed to 12 months. Reference updated.
10/2021	Annual review with no change to clinical coverage criteria. Updated reference.
10/2022	Annual review with no change to clinical coverage criteria. Added state mandate footnote.
10/2023	Annual review. Added Elfabrio as a drug to not be used in combination. Updated reference.
10/2024	Annual review with no change to clinical coverage criteria. Updated reference.