HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Galafold (migalastat)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Galafold 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. It is estimated that the amenable variants are present in 35-50% of the Fabry disease patient population. Galafold is an alternative to enzyme replacement therapy (ERT) and is taken orally. It increases activity of the deficient enzyme instead of replacing it.
Fabry disease is an X-linked lysosomal storage disorder caused by mutations in the GLA gene that cause deficiency of the alpha-galactosidase A (alpha-Gal A) lysosomal enzyme. Normally this enzyme breaks down certain lipids in lysosomes, such as globotriaosylceramide (GL-3). Without it, GL-3 accumulates in blood vessels, the kidneys, heart, nerves, and other organs.

Galafold (migalastat) will be considered for coverage when the following criteria are met:

Fabry Disease

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a medical geneticist, nephrologist, cardiologist, neurologist, or metabolic specialist; AND
3. Member has a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant (refer to package insert) based on in vitro assay data documented in chart notes; AND
4. Member does NOT have severe renal impairment or end-stage renal disease requiring dialysis; AND
5. Galafold will NOT be used in combination with Fabrazyme.
6. **Dosage allowed/Quantity limit:** 123 mg (1 capsule) orally every other day.

   (QL: 14 capsules per 28 days).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show positive clinical response such as stabilized kidney function (e.g., GFR, proteinuria), reduced plasma or tissue GL-3 levels, reduced left ventricular mass index, or other Fabry symptom improvement.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Galafold (migalastat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/20/2019	New policy for Galafold created.
06/18/2021	Transferred to new template. Updated references. Added neurology to specialists. Removed baseline GL-3 level. Removed exclusions except renal impairment and combination therapy. Increased initial approval duration to 6 months and renewal to 12 months. Revised renewal criteria; removed % reductions.
11/22/2022	Annual review. Reorganized summary and added reference.

References:

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