Pharmacy Drug Policy & Procedure

Policy Name:	Galafold (migalastat)	Policy #:	2665P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Galafold (migalastat).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Galafold (migalastat) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of Fabry disease with an amendable GLA variant (confirmed through genetic testing)
1.2 Age 18 years of age or older
1.3 Documentation of baseline number of GL-3 inclusions per kidney interstitial capillary
1.4 Prescribed by a geneticist (genetic disorder doctor) or specialist in the treatment of Fabry disease

2. Exclusion Criteria

2.1 Members with severe kidney impairment (eGFR < 30mL/minute/1.73m2)
2.2 Members with severe end-stage kidney disease requiring dialysis
2.3 Concomitant therapy with either Fabrazyme or Elfabrio

3. Approval Period

3.1 Initial Approval: 12 months
3.2 Reapproval: 12 months with 50% reduction from baseline in the number of GL-3 inclusions per kidney interstitial capillary

CPT Codes

HCPCS Codes

References

1. Galafold (migalastat) [prescribing information]. Philadelphia, PA: Amicus Therapeutics US LLC; June 2024.
2. Benjamin ER, Della Valle MC, Wu X, et al. The validation of pharmacogenetics for the identification of Fabry patients to be treated with migalastat. Genet Med 2017; 19:430.

3. Germain DP, Hughes DA, Nicholls K, et al. Treatment of Fabry's disease with the pharmacologic chaperone migalastat. N Engl J Med. 2016;375(6):545-555.
4. Henderson, N et al. Fabry disease practice resource: Focused revision. J Genet Couns. 2020;29(5):715–717.
5. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018 Apr; 123(4): 416-427.
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