Pharmacy Drug Policy & Procedure

Policy Name:	Fabrazyme (agalsidase beta) and Elfabrio (pegunigalsidase alfa)	Policy #:	2474P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of enzyme replacement therapies used for Fabry disease; Fabrazyme (agalsidase beta) and Elfabrio (pegunigalsidase alfa).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa) under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Fabry disease

1.1 Diagnosis of Fabry disease confirmed by one of the following;
- Gene testing results with significant disease related mutations in the GALA/GLA gene
- Decreased blood levels of alpha-galactosidase A (< 5% of normal)

1.2 Age 2 years or older (Fabrazyme) or 18 years or older (Elfabrio)

1.3 Prescribed by a gene doctor or other specialist in the treatment of Fabry disease

1.4 Documented presence of clinical manifestations (e.g., kidney related, brain/nerve related, heart related)

2. Exclusion Criteria

2.1 Marginal alpha- galactosidase A levels AND a lack of clinical manifestation

2.2 Concomitant therapy of both Fabrazyme and Elfabrio or either in addition to Galafold

3. Approval Period

3.1 Initial: 12 months

3.2 Reauthorization: 12 months with documentation to support clinical benefit from therapy

CPT Codes

HCPCS Codes

J0180	Injection, algalsidase beta, 1mg (Fabrazyme)
J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg (Elfabrio)

References

1. Fabrazyme (agalsidase beta) [prescribing information]. Cambridge, MA: Genzyme Corporation; July 2024.
2. Elfabrio (pegunigalsidase alfa) [prescribing information]. Cary, NC: Chiesi USA; May 2024.
3. Oritz, A et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416–427.
4. Hopkin R, Jefferies J, Laney D, et al. The management and treatment of children with Fabry disease: A United States-based perspective. Molecular Genetics and Metabolism, 2016; 117, 104–113.
5. Henderson, N et al. Fabry disease practice resource: Focused revision. J Genet Couns. 2020;29(5):715–717.

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