

POLICY NAME	Fabrazyme (agalsidase beta) and Elfabrio	POLICY #	2474P
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Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ 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

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)