

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

Coverage Criteria for Fabry disease

- ☐ 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)
- ☐ Age 2 years or older (Fabrazyme) or 18 years or older (Elfabrio)
- ☐ Prescribed by a gene doctor or other specialist in the treatment of Fabry disease
- ☐ Documented presence of clinical manifestations (e.g., kidney related, brain/nerve related, heart related)

Exclusion Criteria – Any of the following prevents coverage

- ☐ Marginal alpha- galactosidase A levels AND a lack of clinical manifestation
- ☐ Concomitant therapy of both Fabrazyme and Elfabrio or either in addition to Galafold