Pharmacy Drug Policy Checklist

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

Criteria

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)

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