Field Name	Field Description
Prior Authorization Group Description	~~Fabrazyme~~**Enzyme Replacement Therapies for Fabry Disease**
Drugs	Fabrazyme (agalsidase beta) **Elfabrio (peguniigalsidase alfa)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	~~Members should be greater than or equal to 2 years of age~~ **According to the FDA approved prescribing information**
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Male members must have a documented diagnosis of Fabry disease confirmed by one of the following: 1. An undetectable (**≤1%** ~~<3%~~) alpha galactosidase A (alpha-Gal-A) activity level OR 2. A deficient ~~(3-35%)~~ alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (*GLA*) gene by molecular genetic testing • Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the *GLA* gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal) • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose

Revision/Review Date: ~~10/2022~~ **7/2023**	**Re-Authorization:** • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose ~~If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.~~ ~~Physician~~**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**