

Medical Policy

Fabry Disease

Last review date: **1/1/2026**

Prior review date: **10/1/2025**

Applicable Products

Elfabrio (Pegunigalsidase alfa-iwx)

Fabrazyme (Agalsidase beta)

Initial Approval Criteria

- Drug-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Elfabrio

- Patient is 18 years of age or older; **AND**
- Documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
 - α -galactosidase A (α -Gal A) activity in plasma, isolated leukocytes, and/or cultured cells (males only); **OR**
 - Detection of pathogenic mutations in the GLA gene by molecular genetic testing; **AND**
- Elfabrio is not prescribed concurrently with agalsidase beta (Fabrazyme) or migalastat (Galafold)

Fabrazyme

- Patient is 2 years of age or older; **AND**
- Documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
 - α -galactosidase A (α -Gal A) activity in plasma, isolated leukocytes, and/or cultured cells (males only); **OR**
 - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso Gb3); **OR**
 - Detection of pathogenic mutations in the GLA gene by molecular genetic testing; **AND**
- Fabrazyme is not prescribed concurrently with pegunigalsidase alfa-iwx (Elfabrio) or migalastat (Galafold)

Renewal Criteria

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity from the drug

Length of Authorization

1 Year

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.