HIGHMARK HEALTH OPTIONS

Updated: 07/2025
Approved: 07/2025

Request for Prior Authorization for Fabry Disease Medications
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

All requests for Fabry disease medications for children under 16 years of age require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Fabry Disease Medications Prior Authorization Criteria:

Fabry disease medications include Fabrazyme (agalsidase beta), or Elfabrio (pegunigalsidase alfa-iwxj). New products with this classification will require the same documentation.

For all requests for Fabry disease medications all of the following criteria must be met:

Coverage may be provided with a diagnosis of Fabry Disease and the following criteria is met:

- Diagnosis has been confirmed by biochemical/genetic confirmation by ONE of the following:
  - α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells.
  - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3).
  - Detection of pathogenic mutations in the alpha-galactosidase A (alpha-Gal A; galactosidase alpha [GLA]) gene by molecular genetic testing.
- Documentation the member is ONE of the following:
  - Symptomatic (i.e. intermittent episodes of burning pain in the extremities (acroparesthesias); cutaneous vascular lesions (angiokeratomas); diminished perspiration (hypo- or anhidrosis); characteristic corneal and lenticular opacities; abdominal pain, nausea, and/or diarrhea of unknown etiology in young adulthood; left ventricular hypertrophy (LVH) or hypertrophic cardiomyopathy of unknown etiology, particularly in young adults; arrhythmias of unknown etiology, particularly in young adults; stroke of unknown etiology at any age; chronic kidney disease (CKD) and/or proteinuria of unknown etiology; multiple renal sinus cysts discovered incidentally)
  - Asymptomatic with ALL of the following:
    - Assigned male at birth
    - Have classic Fabry mutations
  - Documentation of biopsy evidence indicating initiation of therapy is medically necessary.
- Medication must be prescribed by or in association with a metabolic specialist, geneticist, dermatologist, neurologist, nephrologist, rheumatologist, or cardiologist.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria**
  - Chart documentation demonstrating clinical benefit and tolerance to requested medication
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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FABRY DISEASE MEDICATIONS PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: 1-844-325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

How was the member's diagnosis confirmed? (please submit documentation and check one of the following)
☐ α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells.
☐ Plasma or urinary globotriaosylceramide(Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3).
☐ Detection of pathogenic mutations in the GALA/GLA gene by molecular genetic testing.

Please select one of the following:
☐ The member is experiencing symptoms (please submit documentation)
☐ The member is asymptomatic and meets the following criteria:
  ☐ The member was assigned male at birth
  ☐ The member has classic Fabry mutations
☐ The member had a biopsy that showed evidence indicating initiation of enzyme replacement therapy is medically necessary (please submit documentation)

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member tolerated treatment and experience clinical benefit? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE