Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 27, 2024

Elfabrio® (Pegunigalsidase alfa-lwxj)

LENGTH OF AUTHORIZATION: Up to 1 year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of Fabry disease with genetic testing results confirming the presence of an amenable galactosidase alpha gene (GLA) variant.
- Patient must have documented trial and failure on Fabrazyme® unless contraindicated or the patient is intolerant to treatment.
- Medication is prescribed by, or in consultation with a geneticist, endocrinologist, or a physician who specializes in the treatment of lysosomal storage disorders.
- Medication will not be taken concurrently with Fabrazyme® or Galafold®.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 20 mg/10 mL (2 mg/mL) solution in a single-dose vial for injection.