

Clinical Oversight Review Board (CORB) Criteria for Prescribing pegunigalsidase alfa-iwxj (Elfabrio)

Notes:

- Quantity Limits: No

Non-Formulary **pegunigalsidase alfa-iwxj (Elfabrio)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria:

- Prescriber is a geneticist or lysosomal disease specialist, or Fabry disease specialist
- Patient is at least 18 years of age
- Patient has Documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
 - Enzyme assay demonstrating a deficiency of alpha-galactosidase activity α -galactosidase A (α -Gal A); OR
 - Detection of pathogenic mutations in the GLA gene by molecular genetic testing;
AND
- Treatment with agalsidase beta (Fabrazyme) has been ineffective, contraindicated, or not tolerated.

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