Mass General Brigham
Health Plan

Elfabrio (pegunigalsidase alfa-iwxj)
Effective 11/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Elfabrio is indicated for the treatment of adults with confirmed Fabry disease.

Coverage Guidelines
Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members meeting ALL the following criteria:

1. Member has a diagnosis of Fabry disease
2. Medical charts showing diagnosis was confirmed by enzyme assay demonstrating a deficiency in alpha-galactosidase enzyme activity or by genetic testing, or the member is a symptomatic obligate carrier
3. Provider attestation that requested medication will not be used in combination with Galafold or Fabrazyme

Continuation of Therapy
Authorization may be granted for members for continued treatment when medical charts/lab results are provided showing member is responding to therapy (e.g., reduction in plasma globotriaosylceramide [GL-3, Gb3] or GL-3/Gb3 inclusions, improvement and/or stabilization in renal function, pain reduction)

Limitations
1. Initial approvals and reauthorizations will be granted for 12 months

References

1. Elfabrio [package insert]. Cary, NC: Chiesi USA, Inc.; May 2023.
2. Biegstraaten M, Arngrimsson R, Barbey F, et al. Recommendations for initiation and cessation of enzyme replacement therapy in patients with Fabry disease: the European Fabry Working Group consensus document. *Orphanet J Rare Dis.* 2015; 1036.

3. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416-427.

Review History
09/13/2023 - Reviewed at Sept P&T, Effective 11/1/2023