



POLICIES AND PROCEDURE MANUAL

Policy: MBP 289.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Elfabrio (pegunigalsidase alfa-iwxj)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Elfabrio (pegunigalsidase alfa-iwxj)

II. Purpose/Objective:

To provide a policy of coverage regarding Elfabrio (pegunigalsidase alfa-iwxj)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Elfabrio (pegunigalsidase alfa-iwxj) is a recombinant form of the enzyme alpha-galactosidase-A, which catalyzes the hydrolysis of globotriaosylceramide (Gb-3), cleaving a terminal galactose residue from the molecule. Accumulation of globotriaosylceramide (Gb-3) may occur within the tissues of patients with Fabry disease. Pegunigalsidase alfa is internalized and transported into lysosomes exerting enzymatic activity and reducing cellular levels of Gb-3.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Elfabrio (pegunigalsidase alfa-iwxj) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Fabry disease **AND**
- Prescribed by a metabolic specialist with experience in treating Fabry disease

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Elfabrio [prescribing information]. Cary, NC: Chiesi USA Inc; May 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/18/23

Revised: 12/28/23 (references added), 6/30/25 (LOB table, taglines)

Reviewed: 7/8/24

MA UM Committee approval: 12/31/23, 12/31/24, 9/10/25

DHS PARP approval: 8/18/25