Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Enzyme Replacement Therapy for Fabry Disease – Elfabrio (pegunigalsidase alfa-iwxj) and Fabrazyme (agalsidase beta)

Effective: September 15, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration Approved Indications

Elfabrio (pegunigalsidase alfa-iwxj) is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease.

Fabrazyme (agalsidase beta) is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Enzyme Replacement Therapy for Fabry Disease products for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of Fabry disease confirmed by **one (1)** of the following:
    a. Enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity
    b. Genetic test results
    c. The member is a symptomatic obligate carrier

AND

2. The prescribing physician must be a nephrologist, cardiologist, or from a physician specializing in metabolic disorders or genetics

AND

3. Documentation the requested product will not be used concurrently with another enzyme replacement therapy product or Galafold

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg
J0180	Injection, agalsidase beta, 1 mg

References

1. Elfabrio (agalsidase beta) [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.
2. Fabrazyme (agalsidase beta) [package insert]. Cambridge, MA: Genzyme Corporation; June 2024.
3. Biegstraaten, M 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;10(36).
4. Henderson, N et al. Fabry disease practice resource: Focused revision. J Genet Couns. 2020;29(5):715–717.
5. Oritz, A et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416–427

Approval And Revision History

September 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- January 1, 2024: Administrative updated: Added new J Code J2508 to Medical Necessity Guideline.
- August 13, 2024: Updated the Medical Necessity Guideline from “Elfabrio” to Enzyme Replacement Therapy (ERT) for Fabry Disease: Elfabrio, Fabrazyme”. Added existing coverage for Fabrazyme to the Medical Necessity Guideline. Consolidated Tufts Health RITogether and Commercial Products coverage criteria for Elfabrio into same Medical Necessity Guideline (eff 9/1/24).
- June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: No changes
- September 15, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.