Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

# Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), VPRIV (velaglucerase alfa)

*Effective: October 1, 2026*

| | |
|---|---|
| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ 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 (FDA) - Approved Indications**

**Cerezyme (imiglucerase)** is a hydrolytic lysosomal glucocerebrosidase-specific enzyme indicated for treatment of adults and pediatric patients with Type 1 or Type 3 Gaucher disease.

**Elelyso (taliglucerase alfa)** is a hydrolytic lysosomal glucocerebrosidase-specific enzyme indicated for the treatment of patients 4 years and older with a confirmed diagnosis of Type 1 Gaucher disease.

**VPRIV (velaglucerase alfa)** is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy for patients with type 1 Gaucher disease.

**For Commercial Products and Tufts Health Direct: Cerezyme** and **VPRIV** are the preferred Gaucher disease products.

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of **Cerezyme (imiglucerase), Elelyso (taliglucerase alfa)**, or **VPRIV (velaglucerase alfa)** when **ALL** the following criteria are met:

1. One of the following:
    a. For Cerezyme, documented diagnosis of Type 1 or Type 3 Gaucher disease
    b. For Elelyso and VPRIV, **both** of the following:
        i. Documented diagnosis of Type 1 Gaucher disease
        ii. Member is at least 4 years of age

**AND**

2. Documentation of at least **one (1)** of the following conditions:
    a. Anemia
    b. Bone disease

c. Hepatomegaly or splenomegaly
d. Thrombocytopenia

**For Commercial Products and Tufts Health Direct:**

**Elelyso (taliglucerase alfa)**

In addition to the coverage criteria above for Type 1 Gaucher disease:

1. Documented previous failure of or clinical inappropriateness of treatment with Cerezyme or VPRIV

## Limitations

- The Plan does not cover enzyme replacement therapy for Type 2 Gaucher Disease.

## Codes

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

| HCPCS Codes | Description |
|---|---|
| J1786 | Injection, imiglucerase, 10 units |
| J3060 | Injection, taliglucerase alfa, 10 units |
| J3385 | Injection, velaglucerase alfa, 100 units |

## References


1. Anderson HC, et al. Consensus Statement by the International Collaborative Gaucher Group (ICGG) U.S. Coordinators on Individualization of ERT for Type -1 Gaucher Disease. September 2000.
2. Ben Turkia H, Gonzalez DE, Barton NW, et al. Velaglucerase alfa enzyme replacement therapy compared with imiglucerase in patients with Gaucher disease. Am J Hematol. 2013 Mar; 88(3):179-84.
3. Bracoud L, Ahmad H, Brill-Almon E, et al. Improving the Accuracy of MRI Spleen and Liver Volume
4. Measurements: A Phase III Gaucher Disease Clinical Trial Setting as a Model. J BCMD. 2011; 46:47-52.
5. Cerezyme (imiglucerase) [package insert]. Cambridge, MA: Genzyme Corporation; January 2026.
6. Elelyso (taliglucerase alfa injection) [package insert]. New York, NY. Pfizer Labs; December 2025.
7. Vpriv (velaglucerase alfa) [package insert]. Lexington, MA. Takeda Pharmaceuticals. September 2024.
8. Charrow, et al. Gaucher Disease: Recommendations on Diagnosis, Evaluation and Monitoring (Special Article). Archives of Internal Medicine 1998; 158:1754-1760.
9. Cox TM, Drelichman G, Cravo R et al. ENCORE: A multi-national, randomized, controlled, open- label, non-inferiority study comparing eliglustat with imiglucerase in Gaucher disease type 1 patients on enzyme replacement therapy who have reached therapeutic goals. Poster presented at Lysosomal Disease Network World Symposium. San Diego, CA; 2014 February 12.
10. Doneda D, Netto CB, Moulin CC, Schwartz IV. Effects of imiglucerase on the growth and metabolism of Gaucher disease type I patients: a systematic review. Nutr Metab (Lond). 2013 Apr 9; 10(1):34.
11. Therapeutic Goals Using Velaglucerase Alfa in Type 1 Gaucher Disease. Blood Cells Mol Dis. 2011 Jan 15; 46(1):119- 23.
12. Gaucher Disease. Current Issues in Diagnosis and Treatment. JAMA 1996; 275:7 548-553.
13. Gonzalez DE, Turkia HB, Lukina EA, et al. Enzyme replacement therapy with velaglucerase alfa in Gaucher disease: Results from a randomized, double -blind, multinational, Phase 3 study. Am J Hematol. 2013 Mar; 88(3):166-71.
14. Hollak CE. An evidence-based review of the potential benefits of taliglucerase alfa in the treatment of patients with Gaucher disease. Core Evid. 2012; 7:15-20.
15. Hollack CEM, et al. Individualized Low-Dose Alglucerase Therapy for Type 1 Gaucher Disease. The Lancet 1995; 345:1474-1480.
16. National Gaucher Foundation. Gaucher Disease. URL: gaucherdisease.org/what_is.php. Available from Internet. Accessed 2012 August 23.
17. van Dussen L, Cox TM, Hendriks EJ, et al. Effects of switching from a reduced dose imiglucerase to velaglucerase in type 1 Gaucher disease: clinical and biochemical outcomes. Haematologica. 2012 Dec; 97(12):1850-4.
18. Wang RY, Bodamer OA, Watson MS, et al. American College of Medical Genetics: Lysosomal
19. Storage Diseases: Diagnostic Confirmation and Management of Presymptomatic Individuals. Genetics in Medicine. 2011 May; 13(5):464-466.
20. Weinreb NJ, Aggio MC, Andersson HC et al. Gaucher disease type 1: revised recommendations on evaluations and monitoring for adult patients. Semin Hematol. 2004; 41(suppl 5): 15-22.

## Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: Removed the Limitation Coverage will be limited to FDA-approved dosing regimens. Elelyso is a non-preferred product (effective 1/1/2024).
- September 10, 2024: No changes.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- September 9, 2025: Consolidated Commercial/Tufts Health Direct and Tufts Health RITogether MNGs. Effective 10/1/25.
- September 15, 2026: Updated coverage criteria for Cerezyme in adult and pediatric patients with Type 1 or Type 3 Gaucher disease based on expanded indication. Administrative updates: Updated J code for VPRIV. 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.” (eff 10/1/26)

## 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.