Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Tepezza (teprotumumab-trbw)

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 (FDA) Approved Indications

Tepezza (teprotumumab-trbw) is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease (TED).

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Tepezza (teprotumumab-trbw) for Members when the following criteria are met:

1. Documented diagnosis of Graves' disease

AND

2. Documentation of thyroid eye disease

AND

3. Prescribed by or in consultation with an ophthalmologist or endocrinologist

AND

4. Member is at least 18 years of age or older

AND

5. Documentation of an inadequate response or clinical inappropriateness to glucocorticoid therapy

Limitations

- The duration of approval for Tepezza is 8 months.
- The continued use of Tepezza beyond 8 infusions in the patient's lifetime is unproven and not medically necessary.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3241	Injection teprotumumab-trbw 10 mg

References

1. Bartalena L, Baldeschi L, Boboridis K et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of graves' orbitopathy. *Eur Thyroid*. 2016; 5(1): 9-26.
2. Davies TF. Clinical features and diagnosis of Graves‘ orbitopathy (ophthalmopathy). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 28, 2020).
3. Davies TF. Treatment of Graves‘ orbitopathy (ophthalmopathy). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 28, 2020).
4. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the treatment of active thyroid eye disease. N Engl J Med. 2020;382(4):341.
5. Ross DS, Burch HB, Cooper DS et al. 2016 American Thyroid Association Guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. *Thyroid*. 2016; 26(10): 1343-1421.
6. Salvi M, Campi I. Medical treatment of Graves‘ orbitopathy. Horm Metab Res. 2015 Sep;47(10):779-88.
7. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for thyroid -associated ophthalmopathy. N Engl J Med. 2017;376(18):1748.
8. Tepezza (teprotumumab-trbw) [package insert]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; November 2025.
9. Weiler DL. Thyroid eye disease: a review. *Clin Exp Optom*. 2017; 100(1): 20-25.
10. Xu N, Cui Y, Xie T, et al. Comparative efficacy of medical treatments for thyroid eye disease: a network meta-analysis. J Ophthalmol. 2018; 2018:7184163.
11. Zhou X, Zhou D, Wang J, et al. Treatment strategies for Graves‘ ophthalmopathy: a network meta-analysis. Br J Ophthalmol. 2020;104(4):551.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

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

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: May 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- June 13, 2023: Annual review; removed criteria of thyroid eye disease features and Clinical Activity Score of 4 and removed appendix box to reflect new FDA update to indication language, effective September 1, 2023
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- August 13, 2024: Removed the requirements of the patient being euthyroid or mild hypo- or hyperthyroidism. Removed the requirement that the patient does not currently require orbital (eye) surgery and is not planning corrective surgery/irradiation during therapy. Updated the Limitation to be “The continued use of Tepezza beyond 8 infusions in the patient’s lifetime is unproven and not medically necessary.” Clarified that the duration of a Tepezza authorization is 8 months. Minor wording updates (eff 1/1/25).
- July 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.