Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Tepezza™ (teprotumumab-trbw)

Effective: December 12, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

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

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ 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

Graves' orbitopathy is an autoimmune disease of the retroocular tissues occurring in patients with Graves' disease. Although it has often been referred to as Graves' ophthalmopathy, or simply thyroid eye disease (TED), it is primarily a disease of the orbit and is better termed Graves' orbitopathy.

The characteristic signs of Graves' orbitopathy are proptosis (exophthalmos), tearing, and periorbital edema. The degree of proptosis is dependent on the depth of the orbit and the degree of enlargement of the retroocular muscles and retroocular fibrous and fatty tissue. The proptosis may be symmetric, but is often asymmetric, and may be accompanied by a sensation of pressure behind the eyeballs. The proptosis may be partially masked by periorbital edema, which is a common accompaniment. In more severe disease, there may be severe conjunctival inflammation and ulceration from over exposure.

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).

The recommended dose of Tepezza is an intravenous infusion of 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for seven (7) additional infusions.

Clinical Guideline Coverage Criteria

The Plan may cover Tepezza for Members when the following clinical criteria are met:

1. A documented diagnosis of Graves' disease

AND

3. Documentation of active thyroid eye disease

AND

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

AND

5. Member is at least 18 years of age

AND

6. Documentation of **one** of the following:
    a. Member is euthyroid
    b. Member has mild hypo- or hyperthyroidism (free thyroxine [FT4] and free triiodothyronine [FT3] levels < 50% above or below the normal limits)

AND

7. Documentation of an inadequate response, or there is a contraindication or intolerance to glucocorticoid therapy

AND

8. Documentation the Member does not currently require orbital (eye) surgery and is not planning corrective surgery/irradiation during therapy

Limitations

- Continuation of Tepezza beyond eight infusions is considered experimental/investigational 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; October 2021.
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.
- December 12, 2023: No changes. Retire Medical Necessity Guideline effective 1/31/24. Effective February 1, 2024, coverage falls to Unified Medical Policies Medical Necessity Guideline.
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.

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.