Pharmacy Medical Necessity Guidelines: Tepezza™ (teprotumumab-trbw)

Effective: January 18, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT/ MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

All Commercial Products: PRECERT: 617.972.9409

Tufts Health Public Plans Products: MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

The recommended dose of Tepezza (teprotumumab-trbw) 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.

COVERAGE GUIDELINES

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 active moderate to severe thyroid eye disease with at least one of the following:
    a. Lid retraction of at least 2 mm
    b. Moderate or severe soft-tissue involvement
    c. Proptosis at least 3 mm above normal values for race and gender
    d. Periodic or constant diplopia
    e. Mild corneal exposure

AND

3. Documentation of a Clinical Activity Score of at least 4 in the more severely affected eye(s)

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

- Approval is for eight (8) months.
- Continuation of Tepezza (teprotumumab-trbw) beyond eight infusions is considered investigational.

CODES

Code	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; January 2020.
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 HISTORY

May 12, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 12, 2021: Updated coverage criteria from "Documentation of both of the following: Member has not received previous surgical therapy or orbital radiation for thyroid eye disease and Member does not plan on having surgical ophthalmological intervention during treatment with Tepezza" to "Documentation the Member does not currently require orbital (eye) surgery and is not planning corrective surgery/irradiation during therapy."

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of

benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.