

Medical Policy Manual **Approved Rev: Do Not Implement until 9/30/26**

Teprotumumab-trbw (Tepezza®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Tepezza is indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Supporting chart notes or medical record indicating moderate-to-severe disease.

EXCLUSIONS

Coverage will not be provided for repeat series of Tepezza infusions.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an ophthalmologist **or endocrinologist**.

COVERAGE CRITERIA

Thyroid Eye Disease (TED)

Authorization of 6 months may be granted for treatment of TED when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has moderate-to-severe (active and inactive) disease (see Appendix A).
- Member will not exceed a one-time treatment course consisting of 8 infusions given once every 3 weeks (10 mg/kg on first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions).

APPENDIX

Appendix A: Disease Severity Assessment

- Mild disease, at least one of the following:

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- Minor lid retraction (<2 mm)
- Mild soft-tissue involvement
- Exophthalmos <3 mm above normal for race and gender
- No or intermittent diplopia
- Corneal exposure responsive to lubricants
- Moderate-to-severe disease, at least one of the following:
 - Lid retraction ≥ 2 mm
 - Moderate or severe soft-tissue involvement
 - Exophthalmos ≥ 3 mm above normal for race and gender
 - Inconstant or constant diplopia
- Sight-threatening disease, at least one of the following:
 - Dysthyroid optic neuropathy (DON)
 - Corneal breakdown

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Tepezza (Teprotumumab-trbw)	Thyroid Eye Disease	Route of Administration: Intravenous ≥ 18 Years Initial: 10mg/kg once Maintenance: 20mg/kg every 3 weeks for 7 doses

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

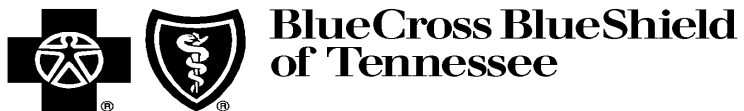
BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Tepezza [package insert]. Deerfield, IL: Horizon Therapeutics USA Inc; **November 2025**.
2. Bartalena L, Kahaly L, Baldeschi L, et al. The 2021 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of Graves' orbitopathy. *Eur J Endocrinol*. 2021. ;185(4):G43-G67.
3. 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.
4. Burch HB, Perros P, Bednarczuk T, Cooper DS, et al. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association. *Thyroid*. 2022 Dec;32(12):1439-1470.
5. ClinicalTrials.gov [Internet]. Bethesda, MD: National Library of Medicine. 2023 March 16 NCT04583735, A Study Evaluating TEPEZZA® Treatment in Patients with Chronic (Inactive) Thyroid Eye Disease; Accessed December 16, 2024.



Policy

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