**Draft Revision Policy: Do Not Implement**

**Teprotumumab-trbw (Tepezza®)**

***Applies to BlueCare Only***

**PROCEDURE CODE(S)** **HCPCS** J3241

**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.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:**

**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.
- Thyroid function tests confirming euthyroid state (laboratory results showing T3 and T4 are within normal limits) OR
- Mild thyroid dysfunction:
  - Lab results showing mild hypothyroidism or hyperthyroidism
  - Evidence of active treatment (e.g., medication, dose adjustments)

**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 and ~~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).
- Member meets one of the following:
  - Member is euthyroid (free triiodothyronine (T3) and thyroxine (T4) levels are within normal limits) OR
  - Member has mild thyroid dysfunction (Free T3 and T4 levels are < 50% above or below normal limits, and member is receiving treatment to normalize thyroid function and maintain a euthyroid state).
- History of intolerance, failure, or contraindication to oral or intravenous glucocorticoids (e.g., prednisone, methylprednisolone).

**APPENDIX**

**Appendix A: Disease Severity Assessment**

- Mild disease, at least one of the following:
  - 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<br>≥18 Years<br>Initial:10mg/kg once<br>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. Accessed June 2026.
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.
6. ClinicalTrials.gov [Internet]. Bethesda, MD: National Library of Medicine. 2024 July 11 NCT03298867, Treatment of Graves' Orbitopathy (Thyroid Eye Disease) to Reduce Proptosis With Teprotumumab Infusions in a Randomized, Placebo-Controlled, Clinical Study (OPTIC); Accessed July 17, 2026.
7. Lexi-Comp Online. (2026, June). AHFS DI. Teprotumumab-trbw. Retrieved June 2026 from Lexi-Comp Online with AHFS.
8. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2026, January). Teprotumumab-trbw. Retrieved June 2026 from MICROMEDEX Healthcare Series.

| | | |
|---|---|---|
| **EFFECTIVE DATE** | 4/1/2020 | (3/10/20 - Approved by P&T Corporate Subcommittee) |
| | 6/2/2021 | (3/9/21 - Approved by P&T Corporate Subcommittee) |
| | 4/30/2022 | (2/8/22 - Approved by P&T Corporate Subcommittee) |
| | 2/14/2023 | (2/14/23 - Maintenance / P&T Corporate Subcommittee) |
| | 8/30/2023 | (6/13/23 - Approved by P&T Corporate Subcommittee) |
| | 1/1/2024 | (10/10/23 - CHS - Approved by P&T Corporate Subcommittee) |
| | 4/1/2024 | (3/12/24 – Approved Maintenance CHS Dosing/ P&T Corporate Subcommittee) |
| | 8/13/2024 | (8/13/24 - Maintenance / P&T Corporate Subcommittee) |
| | 7/8/2025 | (6/13/23 - Approved by P&T Corporate Subcommittee) |
| | 9/30/2026 | (7/14/26 - Approved by P&T Corporate Subcommittee) |

ID_BC_2026