 Approved Rev: Do Not Implement until 1/30/27

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.
- Thyroid function tests confirming euthyroid state (laboratory results showing T3 and T4 are within normal limits per lab standard within the last 6 months) OR
- Mild thyroid dysfunction:
  - Lab results showing mild hypothyroidism or hyperthyroidism (defined as free T3 and T4 levels less than 50% above or below the normal limits within the last 6 months) and chart notes or medical records demonstrating evidence of active treatment (e.g., medication, dose adjustments).

EXCLUSIONS

- Coverage will not be provided for repeat series of Tepezza infusions.
- Member will not use Tepezza in combination with Lumvoa.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an ophthalmologist and 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 or 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 per lab standard) OR
  - Member has mild thyroid dysfunction (Free T3 and T4 levels are < 50% above or below normal limits per lab standard, and member is receiving treatment to normalize thyroid function and maintain a euthyroid state).
- Member has a 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 ≥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).

This document has been classified as public information

REFERENCES

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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.
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EFFECTIVE DATE 1/30/2027

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