

POLICY Document for TEPEZZA (teprotumumab-trbw)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria Tepezza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Tepezza	teprotumumab-trbw	intravenous

Criteria for Approval for Administration in Outpatient Hospital Setting

This policy provides coverage for administration of Tepezza in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Tepezza in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids, other pre-medications)

or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.

- The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
- The member has severe venous access issues that require the use of special interventions only available in the outpatient hospital setting.
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of tocilizumab does not meet the criteria for outpatient hospital infusion, coverage for Tepezza is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable)

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
- Medical records supporting the member is medically unstable
- Medical records supporting the member has severe venous access issues that requires specialized interventions only available in the outpatient hospital setting
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative infusion sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

Specialty Guideline Management Tepezza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tepezza	teprotumumab-trbw

Indications

FDA-approved Indications¹

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.

Coverage Criteria

Thyroid Eye Disease (TED)¹⁻⁵

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 Assessment²

- 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

REFERENCES

SECTION 1

1. Tepezza [package insert]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; July 2023

SECTION 2

1. Tepezza [package insert]. Deerfield, IL: Horizon Therapeutics USA Inc; July 2023.
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.