

SPECIALTY GUIDELINE MANAGEMENT

TEPEZZA (teprotumumab-trbw)

POLICY

I. 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 Indication

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.

II. 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 as applicable to Section V.

III. EXCLUSIONS

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

IV. PRESCRIBER SPECIALTIES

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

V. CRITERIA FOR INITIAL APPROVAL

Thyroid eye disease (TED)

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

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

VI. APPENDIX

Appendix A: Disease Severity Assessment

Reference number(s)
3511-A

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

VII. REFERENCES

1. Tepezza [package insert]. Deerfield, IL: Horizon Therapeutics USA Inc; April 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 2023 April 23.