

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 Indication¹

Tepezza is indicated for the treatment of thyroid eye disease.

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 clinical activity score (CAS) and 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 active disease with a CAS greater than or equal to 4 (see Appendix A)
- C. Member has moderate-to-severe disease (see Appendix B)

VI. APPENDICES

Appendix A: TED Activity Assessment – CAS Elements

Elements*	Score
Painful feeling behind the globe over last 4 weeks	1

Pain with eye movement during last 4 weeks	1
Redness of the eyelids	1
Redness of the conjunctiva	1
Swelling of the eyelids	1
Chemosis (edema of the conjunctiva)	1
Swollen caruncle (flesh body at medial angle of eye)	1

*A 7-point scale with 1-point given for each element present

Appendix B: Disease Severity Assessment

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 ≥ 2 mm
 - b. Moderate or severe soft-tissue involvement
 - c. Exophthalmos ≥ 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]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; January 2020.
2. Bartalena L, Baldeschi L, Kostas B, et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of Graves' orbitopathy. *Eur Thyroid*. 2016;5(1):9-26.
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.