Reference number(s)
4701-A

STANDARD MEDICARE PART B 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 Indications
Tepezza is indicated for the treatment of thyroid eye disease regardless of Thyroid Eye Disease activity or duration.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: 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. 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).

V. APPENDIX

Appendix A: 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

VI. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Tepezza.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. 2016 American Thyroid Association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis.
4. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tepezza are covered.

VII. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VIII. REFERENCES

1. Tepezza [package insert]. Deerfield Lake, IL: Horizon Therapeutics USA Inc; April 2023.
2. Bartalena L, Kahaly GJ, Baldeschi L, et al. The 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy, European Journal of Endocrinology, 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.