



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Tepezza

Page: 1 of 2

Effective Date: 8/17/2023

Last Review Date: 6/2/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Arizona

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Tepezza under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Tepezza

Policy/Guideline:

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 criteria for initial approval.

Exclusions:

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

Prescriber Specialty:

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

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)



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- 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).

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

Approval Duration and Quantity Restrictions:

Approval: 6 months

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.