EVH Clinical Guideline 5063.CC for Tepezza® (teprotumumab-trbw)

Guideline Number:	Applicable Codes	
EVH_CG_5063.CC		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. 		
Original Date:	**Last Revised Date:**	**Implementation Date:**
March 2026	January 2026	March 2026

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for the following drug: Tepezza ® (teprotumumab-trbw)

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL REVIEW CRITERIA

The request must meet all the criteria listed below.

- Must be age 18 years or older
- Must be prescribed by, or in consultation with, an ophthalmologist or endocrinologist
- Must have chart note documentation supporting a diagnosis of both the following:
  - Graves' Disease
  - Moderate to severe Thyroid Eye Disease (TED) [also known as Graves' Ophthalmopathy, Graves' Orbitopathy, Thyroid-Associated Ophthalmopathy (TAO)]
- Must have ONE of the following:
    - Lid retraction ≥ 2 mm
    - Moderate or severe soft tissue involvement
    - Proptosis ≥ 3 mm above normal for race and gender
    - Inconstant or constant diplopia
- Must submit laboratory screening/results or imaging documentation of ALL the following, **collected within the last 3 months:**
  - For diabetic members, HbA1C < 9.0%

- Free thyroxine (FT4 and free triiodothyronine (FT3) levels <50% above or below normal limit
- For women of child-bearing age: negative pregnancy test

- Must have documentation of intolerance, contraindication to, or trial and failure of glucocorticoid therapy for at least 12 weeks
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must have documentation or an attestation from the prescriber for the following
  - Member does not have optic neuropathy or corneal decompensation unresponsive to medical management
  - Member has had hearing assessed prior to therapy with Tepezza and will continue to have hearing assessed during and after treatment with Tepezza
  - If member is of child-bearing age: the member has been counseled on using appropriate forms of contraception prior to initiation, during treatment, and for at least 6 months following the last dose of Tepezza

REAUTHORIZATION CRITERIA

Tepezza is not eligible for reauthorization beyond 8 total infusions.

APPROVAL DURATIONS

Initial Authorization	Up to 6 months
Reauthorization	N/A

CODING AND STANDARDS

Codes

Code	Brand	Description
J3241	Tepezza	Injection, teprotumumab-trbw, 10 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
January 2026	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Tepezza (teprotumumab-trbw) [prescribing information]. Dublin, Ireland: Horizon Therapeutics
2. Douglas RS, Kahaly GJ, Patel A, Sile S, Thompson EHZ, Perdok R, Fleming JC, Fowler BT, Marcocci C, Marinò M, Antonelli A, Dailey R, Harris GJ, Eckstein A, Schiffman J, Tang R, Nelson C, Salvi M, Wester S, Sherman JW, Vescio T, Holt RJ, Smith TJ. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020 Jan 23;382(4):341-352. doi: 10.1056/NEJMoa1910434. PMID: 31971679.
3. Smith TJ, Kahaly GJ, Ezra DG, Fleming JC, Dailey RA, Tang RA, Harris GJ, Antonelli A, Salvi M, Goldberg RA, Gigantelli JW, Couch SM, Shriver EM, Hayek BR, Hink EM, Woodward RM, Gabriel K, Magni G, Douglas RS. Teprotumumab for Thyroid-Associated Ophthalmopathy. N Engl J Med. 2017 May 4;376(18):1748-1761. doi: 10.1056/NEJMoa1614949. PMID: 28467880; PMCID: PMC5718164.