

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Tepezza (teprotumumab-trbw)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Tepezza is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease (TED), also known as Graves' orbitopathy (GO). It binds to IGF-1R and blocks its activation and signaling. Tepezza was the first drug approved by the FDA for TED, approved in 2020. Hyperthyroidism of autoimmune origin is referred to as Graves' disease. TED occurs in some of these patients, causing inflammation and tissue expansion behind the eye leading to proptosis (bulging eyes), often accompanied by diplopia. Most cases are classified as mild; however, blindness is possible in severe cases. The mainstay medical therapy for moderate to severe TED is glucocorticoids.

Tepezza (teprotumumab-trbw) will be considered for coverage when the following criteria are met:

Thyroid Eye Disease (TED)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist or endocrinologist; AND
3. Member has a documented diagnosis of moderate to severe thyroid eye disease (TED) with at least one of the following:
 - a) Proptosis ≥ 3 mm above normal for race and gender
 - b) Moderate or severe soft tissue involvement
 - c) Diplopia
 - d) Orbital pain and/or pressure
 - e) Lid retraction ≥ 2 mm; AND
4. Chart notes must show the member is euthyroid or mildly hypo- or hyper-thyroid (defined as having free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the reference normal limits) prior to starting therapy; AND
5. Member does NOT have sight-threatening TED such as severe optic neuropathy or corneal breakdown.
6. **Dosage allowed/Quantity limit:** 10mg/kg initial dose intravenously followed by seven 20mg/kg infusions every 3 weeks (total of 8 infusions).

If all the above requirements are met, the medication will be approved for 24 weeks.

For **reauthorization**: Retreatment will not be authorized due to a lack of robust literature available to support the use of Tepezza beyond 24 weeks.

CareSource considers Tepezza (teprotumumab-trbw) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/22/2020	New policy for Tepezza created.
02/24/2022	Transferred to new template. Updated references. Added definition of moderate to severe disease, made CAS a separate point. Added endocrine as a specialist. Removed "high dose" from steroid trial; regimen may vary.
04/20/2023	Updated references. Updated policy to allow treatment of TED regardless of disease activity or duration (per phase 4 study and label update); previously only allowed for active disease. Removed CAS score requirement, added exclusion of sight-threatening TED, added orbital pain/pressure as qualifier, removed steroid trial.

References:

1. Tepezza Prescribing Information. Lake Forest, IL: Horizon Therapeutics USA, Inc.; 2023.
2. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. *N Engl J Med*. 2020;382(4):341-352. doi:10.1056/NEJMoa1910434
3. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. *N Engl J Med*. 2017;376(18):1748-1761. doi:10.1056/NEJMoa1614949
4. 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. *Eur J Endocrinol*. 2021;185(4):G43-G67. Published 2021 Aug 27. doi:10.1530/EJE-21-0479
5. Winn BJ, Kersten RC. Teprotumumab: Interpreting the Clinical Trials in the Context of Thyroid Eye Disease Pathogenesis and Current Therapies. *Ophthalmology*. 2021;128(11):1627-1651. doi:10.1016/j.ophtha.2021.04.024
6. Douglas RS, Kahaly GJ, Ugradar S, et al. Teprotumumab Efficacy, Safety, and Durability in Longer-Duration Thyroid Eye Disease and Re-treatment: OPTIC-X Study. *Ophthalmology*. 2022;129(4):438-449. doi:10.1016/j.ophtha.2021.10.017
7. IPD Analytics; Accessed April 20, 2023.
8. A Study Evaluating TEPEZZA® Treatment in Patients With Chronic (Inactive) Thyroid Eye Disease. ClinicalTrials.gov Identifier: NCT04583735. Updated April 11, 2023. Accessed April 19, 2023. Available at: <https://clinicaltrials.gov/ct2/show/NCT04583735?cond=tepezza&draw=2&rank=1>
9. Burch HB, Perros P, Bednarczuk T, et al. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association. *Thyroid*. 2022;32(12):1439-1470. doi:10.1089/thy.2022.0251
10. Nie T, Lamb YN. Teprotumumab: A Review in Thyroid Eye Disease [published correction appears in *Drugs*. 2022 Dec 2;]. *Drugs*. 2022;82(17):1663-1670. doi:10.1007/s40265-022-01804-1
11. Douglas RS, Kossler AL, Abrams J, et al. Expert Consensus on the Use of Teprotumumab for the Management of Thyroid Eye Disease Using a Modified-Delphi Approach. *J Neuroophthalmol*. 2022;42(3):334-339. doi:10.1097/WNO.0000000000001560
12. Douglas RS, Dailey R, Subramanian PS, et al. Proptosis and Diplopia Response With Teprotumumab and Placebo vs the Recommended Treatment Regimen With Intravenous Methylprednisolone in Moderate to Severe Thyroid Eye Disease: A Meta-analysis and Matching-Adjusted Indirect Comparison. *JAMA Ophthalmol*. 2022;140(4):328-335. doi:10.1001/jamaophthalmol.2021.6284

Effective date: 10/01/2023

Revised date: 04/20/2023