

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Tepezza (teprotumumab-trbw)
BILLING CODE	J3241
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home infusion/Office/Outpatient hospital/Infusion center
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

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist or endocrinologist; AND
3. Member has a confirmed diagnosis of Graves' disease; AND
4. Member has active moderate to severe thyroid eye disease (TED) with 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) diplopia; AND
5. Member has a Clinical Activity Score (CAS) of 4 or greater documented in chart notes; AND
6. 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
7. Member has tried and failed a 12-week course of a systemic corticosteroid (e.g. methylprednisolone) or has a significant intolerance or contraindication to corticosteroids.
8. **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.

References:

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2. NCT03461211 in ClinicalTrials.gov. NIH U.S. National Library of Medicine. Accessed April 22, 2020.
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 [published correction appears in *Thyroid*. 2017 Nov;27(11):1462]. *Thyroid*. 2016;26(10):1343-1421. doi:10.1089/thy.2016.0229
4. Bartalena L, Baldeschi L, Boboridis K, Eckstein A, Kahaly G, J, Marcocci C, Perros P, Salvi M, Wiersinga W, M: The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. *Eur Thyroid J* 2016;5:9-26. doi: 10.1159/000443828.
5. 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
6. 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
7. IPD Analytics; Accessed February 24, 2022.
8. 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
9. 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 [published online ahead of print, 2021 Oct 21]. *Ophthalmology*. 2021;S0161-6420(21)00818-6. doi:10.1016/j.ophtha.2021.10.017

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Revised date: 02/24/2022