

Tepezza (teprotumumab-trbw)

Override(s)	Approval Duration
Prior Authorization	*One course of treatment; defined as a total of 8 intravenous infusions of Tepezza (teprotumumab-trbw) administered every 3 weeks

Medications	Dosing Limit
Tepezza (teprotumumab-trbw) 500 mg vial	Initial dose: One 10 mg/kg infusion Subsequent doses: 20mg/kg every 3 weeks for seven infusions

APPROVAL CRITERIA

Requests for one course* of Tepezza (teprotumumab-trbw) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Thyroid Eye Disease; **AND**
- II. Tepezza (teprotumumab-trbw) is prescribed by, or in consultation with an endocrinologist **AND** an ophthalmologist; **AND**
- III. Documentation is provided that individual has moderate to severe disease, as defined by the following:
 - A. For individuals with symptomatic, active disease, one of the following (Douglas 2020):
 1. Lid retraction ≥ 2 mm; **OR**
 2. Moderate or severe soft tissue involvement; **OR**
 3. Proptosis ≥ 3 mm above normal values for race and sex; **OR**
 4. Intermittent or constant diplopia; **AND**
 - B. For individuals with stable, chronic (inactive) TED, one of the following (Douglas 2023):
 1. Greater than or equal to 3 mm increase in proptosis from before diagnosis of TED; **OR**
 2. Proptosis \geq to 3 mm above normal values for race and sex;

AND

- IV. Documentation is provided that one of the following applies:
 - A. Thyroid function tests are provided and are within normal limits as defined by laboratory standard (i.e. individual is euthyroid); **OR**
 - B. Thyroid function tests show free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below normal limits as defined by laboratory standard.

Tepezza (teprotumumab-trbw) may not be approved for the following:

- I. More than one course* of treatment; **OR**

- II. Individual is using Tepezza to reduce proptosis for cosmetic reasons alone; **OR**
- III. Individual has had prior orbital irradiation or eye surgery for TED; **OR**
- IV. Individual has decreased best-corrected visual acuity due to optic neuropathy as defined by decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect; **OR**
- V. Individual has unresponsive corneal decompensation; **OR**
- VI. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. 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; 26:1343-1421. Erratum in: *Thyroid*. 2017 Nov;27(11):1462
5. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. *N Engl J Med*. 2017; 376: 1748-1761.
6. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. *N Engl J Med*. 2020; 382: 341-352.
7. 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
8. Douglas RS, Couch S, Wester ST, et al. Efficacy and Safety of Teprotumumab in Patients With Thyroid Eye Disease of Long Duration and Low Disease Activity. *J Clin Endocrinol Metab*. 2023;109(1):25-35. doi:10.1210/clinem/dgad637
9. Bartalena L, Kahaly G, 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*. 2021; 185(4), G43-G67.
10. 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 Dec;32(12):1439-1470. doi: 10.1089/thy.2022.0251.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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