

Tepezza™ (teprotumumab-trbw)

When requesting Tepezza™ (teprotumumab-trbw), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Tepezza is indicated for the treatment of thyroid eye disease, regardless of thyroid eye disease activity or duration.

Coverage Guidelines

Thyroid Eye Disease (Note: Thyroid Eye Disease is also recognized as Graves' ophthalmopathy, Graves' orbitopathy, thyroid-associated ophthalmopathy, and thyroid orbitopathy)

An individual must meet **ALL** of the following criteria for approval:

- Has been assessed as having disease of at least moderate severity based on signs and symptoms (e.g., the degree of inflammation, degree of proptosis, presentation of diplopia, etc.);
Note: Examples of signs and symptoms of disease of at least moderate severity include the following: lid retraction ≥ 2 mm, moderate or severe soft tissue involvement, proptosis ≥ 3 mm above normal for race and sex, and diplopia (Gorman score 2 to 3)
- Is 18 years of age or older;
- Tepezza is prescribed by or in consultation with an ophthalmologist, endocrinologist, or a physician who specializes in thyroid eye disease;
- Has not received a total 8 doses of Tepezza.

Approval duration: 6 months

Dosing Recommendation

The recommended dose of Tepezza is an intravenous infusion of 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for 7 additional infusions.

References

1. Tepezza injection [prescribing information]. Lake Forest, IL: Horizon Therapeutics; July 2023.
2. Horizon. Teprotumumab for injection. Briefing document for the Food and Drug Administration Dermatologic and Ophthalmic Drugs Advisory Committee. Meeting Date: December 13, 2019. Available at: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-public-participation-information-december-13-2019-meeting-dermatologic-and-ophthalmic-drugs#event-information>. Accessed on January 4, 2025.
3. Bartley GB, Fatourehchi V, Kadrmas EF, Jacobsen SJ, Ilstrup DM, Garrity JA, Gorman CA. Clinical features of Graves' ophthalmopathy in an incidence cohort. *Am J Ophthalmol* 1996;121(3):284-290.
4. 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. Epub 2022 Dec 8.
5. Shan S, Douglas R. The pathophysiology of thyroid eye disease. *J Neuroophthalmol*. 2014 Jun;34(2):177-85.