

Tepezza™ (teprotumumab-trbw)

When requesting Tepezza™ (teprotumumab-trbw), the individual requiring treatment must be diagnosed with an 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 active disease of at least moderate severity based on signs and symptoms (e.g., the degree of inflammation, degree of proptosis, presentation of diplopia, etc.);
- 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 December 19, 2023.
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. Shan S, Douglas R. The pathophysiology of thyroid eye disease. J Neuroophthalmol. 2014 Jun;34(2):177-85.
5. Horizon Therapeutics. A study evaluating Tepezza treatment in patients with chronic (inactive) thyroid eye disease. In: ClinicalTrials.gov [internet]. Bethesda (MD): National Library of Medicine (US). 2023-04-20. Available at: <https://clinicaltrials.gov/ct2/show/NCT04583735?cond=tepezza&draw=2&rank=1>. NCT04583735. Accessed on December 19, 2023.
6. Horizon Therapeutics, press release. Horizon Therapeutics plc announces positive topline data from Tepezza (teprotumumab-trbw) phase 4 clinical trial in patients with chronic/low clinical activity score (CAS) thyroid eye disease (TED). Released April 10, 2023. Available at: [Horizon Therapeutics plc Announces Positive Topline Data from TEPEZZA® \(teprotumumab-trbw\) Phase 4 Clinical Trial in Patients with Chronic/Low Clinical Activity Score \(CAS\) Thyroid Eye Disease \(TED\) | Horizon Therapeutics plc \(gcs-web.com\)](#). Accessed on December 19, 2023.

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