

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.

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

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; January 2020.
2. Wang Y, Smith TJ. Current concepts in the molecular pathogenesis of thyroid-associated ophthalmopathy. *IOVS*. 2014;55(3):1735-1748.
3. Douglas RS. Teprotumumab, an insulin-like growth factor-1 receptor antagonist antibody, in the treatment of active thyroid eye disease: a focus on proptosis. *Eye*. 2019;33(2):183-90.
4. 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 7, 2020.
5. 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.
6. Shan S, Douglas R. The pathophysiology of thyroid eye disease. *J Neuroophthalmol*. 2014 Jun;34(2):177-85.