

## PRIOR AUTHORIZATION POLICY

- POLICY:** Ophthalmology – Tepezza Prior Authorization Policy
- Tepezza™ (teprotumumab intravenous infusion – Horizon)

**REVIEW DATE:** 01/18/2023

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### OVERVIEW

Tepezza, an insulin-like growth factor-1 receptor (IGF-1R) antagonist, is indicated for the treatment of thyroid eye disease.<sup>1</sup>

### Disease Overview

Thyroid eye disease is a progressive, vision-threatening autoimmune inflammatory disease of the eye and orbital tissues with predominant features of fibrosis and adipogenesis.<sup>2</sup> It is also recognized in literature as Graves' ophthalmopathy, Graves' orbitopathy, thyroid-associated ophthalmopathy, and thyroid orbitopathy. Thyroid eye disease is most commonly related to Graves' disease, it can also develop in patients with other thyroid diseases (e.g., Hashimoto's thyroiditis) and has a higher prevalence in women than men (16 per 100,000 vs. 3 per 100,000, respectively).<sup>3</sup> In active disease, orbital fibroblasts appear responsible for soft tissue enlargement by expressing potential pathogenic autoantigens, such as thyrotropin receptor and IGF-1R.<sup>2</sup> Activation of orbital fibroblasts leads to increased hyaluronic acid production, proinflammatory cytokine synthesis, and enhanced differentiation into either myofibroblasts or adipocytes. These processes result in inflammation, enlargement of extraocular muscles and expansion of orbital tissue and fat, which in turn cause forward displacement of the eye, resulting in proptosis and inflammation.<sup>4</sup> The degree of severity can be staged as mild, moderate-to-severe, or sight-threatening, following quantitative assessment of lid aperture width, proptosis measurement, diplopia score, degrees of abduction in eye muscle movement, examination of the cornea for evidence of exposure keratitis or ulceration, and assessment of optic nerve function.

### Dosing Information

The recommended dose is 10 mg/kg administered by intravenous (IV) infusion for the initial dose, followed by 20 mg/kg administered intravenously once every 3 weeks for seven additional doses.<sup>1</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tepezza. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tepezza as well as the monitoring required for adverse events and long-term efficacy, approval requires Tepezza to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

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## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tepezza is recommended in those who meet the following criteria:

### FDA-Approved Indication

1. **Thyroid Eye Disease.** Approve for 6 months if the patient meets the following criteria (A, B, C, and D):

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

A) Patient is  $\geq 18$  years of age; AND

B) Patient has been assessed as having active disease of at least moderate severity based on signs and symptoms, according to the prescriber; AND

Note: Examples of active disease of at least moderate severity include the degree of inflammation, degree of proptosis, presentation of diplopia.

C) Patient has not received 8 doses (total) of Tepezza; AND

Note: The maximum recommended treatment is for 8 doses. For a patient who has started therapy but has not completed 8 doses, approve the number of doses required for the patient to receive a total of 8 doses.

D) The medication is prescribed by or in consultation with an ophthalmologist, endocrinologist, or a physician who specializes in thyroid eye disease.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tepezza is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Tepezza intravenous infusion [prescribing information]. Lake Forest, IL: Horizon; December 2022.
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 10, 2023.
3. Bartley GB, Fatourehchi V, Kadrmas EF, et al. 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.