

Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Tepezza	Drug Generic Name:	Teprotumumab-trbw
J Code:	J3241 (IV)	1 billable unit =	10 mg
Original Date of Review:	08/01/2024	Last Reviewed:	8/1/2024
Revision Date History			

Teprotumumab-trbw, an insulin like growth factor-1 receptor inhibitor (IGF-1R), is a fully human IgG1 monoclonal antibody that binds to IGF-1R and blocks activation and signaling. It is used to treat Thyroid Eye Disease (TED), otherwise known as Grave's Orbitopathy or thyroid associated orbitopathy.

Criteria:

- **Length of authorization (LOA):**
 - **Initiation:** Maximum 8 doses per lifetime
 - For patients who began therapy prior to coming on plan, but did not complete all 8 doses, approval will only be provided to achieve up to a total of 8 doses.
 - **Renewal:** Cannot be renewed
- **Age:** At least 18 years of age
- **Diagnoses:**
 - Thyroid Eye Disease (Moderate to Severe)
- **Quantity Limit:**
 - Tepezza 500 mg vial
 - Loading: 10 mg/kg at weeks 0
 - Maintenance: 20 mg/kg every 3 weeks for 7 doses
- **Initial Approval Criteria**
 - **Universal Criteria**
 - Patient is at least 18 years of age; **AND**
 - Prescribed by an endocrinologist **OR** an ophthalmologist; **AND**
 - Will not be used in combination with another biologic immunomodulator e.g. rituximab, tocilizumab, sarilumab **AND**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial to oral or intravenous glucocorticoids (e.g. methylprednisolone, prednisone); **AND**
 - **Indication Specific Criteria**
 - **Thyroid Eye Disease**
 - Patient has moderate to severe thyroid eye disease as defined by the following:
 - Lid retraction \geq 2mm; **OR**
 - Moderate or severe soft tissue involvement; **OR**
 - Proptosis \geq 3 mm above normal values for race and sex; **OR**
 - Intermittent or constant diplopia; **AND**
 - Documentation is provided that one of the following applies:
 - Individual is not using Tepezza to reduce proptosis for cosmetic reasons alone; **AND**
 - Individual has not had prior orbital irradiation or eye surgery for TED; **AND**

- Individual does not have 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; **AND**
 - Individual does not have unresponsive corneal decompensation; **AND**
 - Thyroid function tests are provided and are within normal limits as defined by laboratory standard (i.e. individual is euthyroid); **OR**
 - 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.
- **Renewal Criteria**
 - **Thyroid Eye Disease**
 - The clinical benefit of Tepezza has not been demonstrated beyond 8 infusions in phase 3 clinical trials. The continued use of Tepezza beyond 8 infusions in the patient’s lifetime is presently unproven and not medically necessary.

- **Dosage/Administration**

Tepezza (IV)	
Indication	Dose (Intravenous administration)
Thyroid Eye Disease (Moderate to Severe)	<u>Adult Loading Dose:</u> - 10 mg/kg at weeks 0 <u>Adult Maintenance Dose:</u> - 20 mg/kg every 3 weeks x 7 doses

NDC:

- Tepezza 500 mg single-dose vial (SDV): 75987-0130-15

References:

1. Tepezza [prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; April 2023.
2. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. *N Engl J Med.* 2020 Jan 23;382(4):341-352.
3. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. *N Engl J Med.* 2017 May 4;376(18):1748-1761.
4. Hodgson NM and Rajaii F. Current Understanding of the Progression and Management of Thyroid Associated Orbitopathy: A Systematic Review. *Ophthalmol Ther.* 2019 Dec 10.
5. Bartalena L, Kahaly G, Baldeschi L, European Group on Graves’ Orbitopathy (EUGOGO), et al. The 2021 European Group on Graves’ Orbitopathy Clinical Practice Guidelines for the Medical Management of Graves’ Orbitopathy. *Eur Endocrinology J.* 2021; 185(4), G43-G67.
6. 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). 2023. Available at <https://www.tepezza.com>. Accessed May 2, 2023.
7. A Study Evaluating Tepezza Treatment in Patients with Chronic (Inactive) Thyroid Eye Disease. ClinicalTrials.gov identifier: NCT04583735. Updated April 11, 2023. Accessed May 2, 2023.

Appendix 1 – Covered Diagnosis Codes - Intravenous (J3241)

ICD-10	ICD-10 Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm