

Tepezza® (teprotumumab-trbw) (Intravenous)

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I. Length of Authorization ¹

- Initial: Prior authorization validity will be provided initially for 6 months (max total of 8 infusions).
- Renewal: Prior authorization validity may NOT be renewed.*

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 150 billable units initially followed by 250 billable units every 3 weeks for 7 additional doses

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹⁻³

- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology; **AND**
- Patient has not had a decrease in best corrected visual acuity (BCVA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement); **AND**
- Patient is euthyroid [Note: mild hypo- or hyperthyroidism is permitted which is defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits (every effort should be made to correct the mild hypo- or hyperthyroidism promptly)]; **AND**
- Patient does not have corneal decompensation that is unresponsive to medical management; **AND**
- Patient does not have uncontrolled diabetes; **AND**
- Patient hearing will be assessed before, during, and after treatment; **AND**
- Used as single agent therapy; **AND**

Thyroid Eye Disease (TED) † Φ ^{1-8,10,13}

- Patient has a clinical diagnosis of TED based on characteristic clinical signs and features in the context of autoimmune thyroid disease; **AND**

- Patient has active disease; **AND**
 - Patient has moderate-to-severe TED as defined by one of the following:
 - Clinical Activity Score (CAS) ≥ 4 §
 - severe proptosis (≥ 3 mm)
 - intermittent or constant diplopia
 - moderate or severe soft tissue involvement
 - orbital pain and/or pressure; **OR**
 - Patient had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids; **OR**
- Patient has inactive disease; **AND**
 - Patient has a lid retraction of ≥ 2 mm; **AND**
 - Patient has mild or early optic neuropathy with close clinical observation

§ Assessment of Thyroid Eye Disease (TED): Clinical Activity Score (CAS) Elements ¹¹

- Spontaneous retrobulbar pain
- Pain on attempted upward or downward gaze
- Redness of eyelids
- Redness of conjunctiva
- Swelling of caruncle or plica
- Swelling of eyelids
- Swelling of conjunctiva (chemosis)
- Increase in exophthalmos of ≥ 2 mm*
- Decrease in eye motility of $\geq 8^\circ$ **
- Decrease in visual acuity in the last 1–3 months*

*Note: Each element is assigned a score of one. Elements denoted with a * can be used when a previous assessment is available. A seven-point scale is used when prior assessment is not available.*

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹

Duration of authorization has not been exceeded (*refer to Section I*)*

**Re-treatment with Tepezza will be reviewed on a case-by-case basis.*

V. Dosage/Administration ¹

Indication	Dose
Thyroid Eye Disease	Administer 10 mg/kg intravenously initially, then 20 mg/kg intravenously every three weeks for 7 additional infusions (8 infusions total). Administer the diluted solution intravenously over 90 minutes for the first two infusions. If well tolerated, the minimum time for subsequent infusions can be reduced to 60 minutes. If not well tolerated, the minimum time for subsequent infusions should remain at 90 minutes.

VI. Billing Code/Availability Information

HCPCS code:

- J3241 – Injection, teprotumumab-trbw, 10 mg: 1 billable unit = 10 mg

NDC:

- Tepezza 500 mg single-dose vial for injection: 75987-0130-xx

VII. References

1. Tepezza [package insert]. Dublin, Ireland; Horizon Therapeutics Ireland, DAC; November 2024. Accessed July 2025.
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4. Patel A, Yang H, Douglas RS. Perspective: A New Era in the Treatment of Thyroid Eye Disease. *Am J Ophthalmol* 2019;208:281–288.
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12. Burch H, 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®*. 13 Dec 2022. 1439-1470. <http://doi.org/10.1089/thy.2022.0251>

13. Douglas RS, Kossler AL, Abrams J, Briceño CA, et al. Expert Consensus on the Use of Teprotumumab for the Management of Thyroid Eye Disease Using a Modified-Delphi Approach. J Neuroophthalmol. 2022 Sep 1;42(3):334-339. doi: 10.1097/WNO.0000000000001560. Epub 2022 Mar 24. PMID: 35421877; PMCID: PMC9377484.

Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC