

Tepezza® (teprotumumab-trbw) (Intravenous)

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I. Length of Authorization ¹

Coverage will be provided for 6 months (max total of 8 infusions) and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Tepezza 500 mg single-dose vial for injection: 3 vials for initial dose followed by 5 vials for each of 7 additional doses

B. 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

Site of care specialty infusion program requirements are met (refer to [Moda Site of Care Policy](#)).

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 that is related to Graves' Disease (i.e., Graves' orbitopathy); **AND**
 - Patient has active disease; **AND**
 - Patient had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids; **OR**
 - Patient has inactive disease

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

IV. Renewal Criteria¹

Coverage cannot be renewed.

V. Dosage/Administration¹

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; July 2023. Accessed November 2023.
2. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. N Engl J Med 2017; 376:1748-1761. DOI: 10.1056/NEJMoa1614949
3. Douglas RS, Sile S, Thompson EH, et al. Teprotumumab Treatment Effect on Proptosis in Patients With Active Thyroid Eye Disease; Results From a Phase 3, Randomized, Double-Masked, Placebo-Controlled, Parallel-Group, Multicenter Study. Amer Assoc of Clin Endo. Los Angeles: Endocrine Practice; 2019.

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.
5. Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis. *Thyroid*. 2016;26(10):1343 -1421.
6. Mourits MP, Koornneef L, Wiersinga WM, et al. Clinical criteria for the assessment of disease activity in Graves' ophthalmopathy: a novel approach. *Br J Ophthalmol*. 1989 Aug; 73(8): 639–644.
7. Mourits MP, Prummel MF, Wiersinga WM, et al. Clinical activity score as a guide in the management of patients with Graves' ophthalmopathy. *Clin Endocrinol (Oxf)*. 1997 Jul;47(1):9-14.
8. Bartalena L, Baldeschi L, Boboridis K, et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. *Eur Thyroid J*. 2016 Mar;5(1):9-26.
9. Ye X, Bo X, Hu X, et al. Efficacy and safety of mycophenolate mofetil in patients with active moderate-to-severe Graves' orbitopathy. *Clin Endocrinol (Oxf)*. 2017;86(2):247.
10. Zang S, Ponto KA, Kahaly GJ. Intravenous Glucocorticoids for Graves' Orbitopathy: Efficacy and Morbidity. *J Clin Endocrinol Metab*. 2011 Feb;96(2):320-32.
11. Bartalena L, Kahaly G, Baldeschi L, et al. The 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy. *European Journal of Endocrinology*. 27 Aug 2021. <https://doi.org/10.1530/EJE-21-0479>
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>

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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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