Tepezza® (teprotumumab-trbw)
(Intravenous)

Effective Date: 08/01/2020
Review Date: 07/27/2020, 06/24/2021, 5/5/2022, 7/13/2023, 12/07/2023, 01/04/2024, 6/26/2024, 05/21/2025, 03/10/2026

Scope: Medicaid*, Commercial, Medicare
*** Effective 12/1/2023 Medication only available on the Pharmacy Benefit**

I. Length of Authorization

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]:

- 115 billable units initially followed by 230 billable units every 3 weeks thereafter for a total of 8 doses

III. Summary of Evidence

Tepezza (teprotumumab-trbw) is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of thyroid eye disease (TED), a rare autoimmune condition characterized by inflammation and swelling in the tissues behind the eyes. Clinical studies, including OPTIC and EMA-reviewed trials, demonstrated significant improvement in proptosis and disease activity. In one study, 69% of patients responded compared to 20% with placebo, and in the OPTIC trial, 83% showed reduced eye bulging. The most common adverse effects include muscle spasms, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dry skin, dysgeusia, headache, weight decreased, and nail disorders.

IV. Initial Approval Criteria [1,2,3,4]

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Member is at least 18 years old; **AND**

- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology; **AND**
- Member 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**
- Member does not have corneal decompensation that is unresponsive to medical management; **AND**
- Member does not have poorly controlled diabetes; **AND**
- Must be used as single agent therapy and Tepezza cannot be used for retreatment**; AND**
- Member's dose does not exceed 10 mg/kg intravenously initially, then 20 mg/kg IV every three weeks

Thyroid Eye Disease (TED) †

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

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s)

V. Renewal Criteria

Coverage cannot be renewed.

VI. Dosage/Administration

Indication	Dose
Thyroid Eye Disease	10 mg/kg intravenously initially, then 20 mg/kg IV every three weeks for 7 additional infusions 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.

VII. 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

VIII. References

1. Tepezza [package insert]. Dublin, Ireland; Horizon Therapeutics Ireland, DAC, November 2025. Accessed March 2026.
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 EHZ, 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.
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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm (hyperthyroidism)
H05.83	Thyroid orbitopathy (or Thyroid Eye Disease – TED)
H05.831	Thyroid orbitopathy, right orbit
H05.832	Thyroid orbitopathy, left orbit
H05.833	Thyroid orbitopathy, bilateral
H05.839	Thyroid orbitopathy, unspecified orbit

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

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

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

Policy Rationale:

Tepezza was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Tepezza according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.