Effective date: 8/1/2020
Last Reviewed: 07/27/2020, 06/24/2021, 5/5/2022, 7/13/2023, 9/14/2023, 12/07/2023, 01/04/2024, 5/21/2025 Pharmacy Scope: Medicaid**(Pharmacy Benefit ONLY) Medical Scope: Commercial, Medicare Medicaid Plan (MMP)

Tepezza® (teprotumumab-trbw)
(Intravenous)

Scope: Medicaid**

*** *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 per 21 days 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. Initial Approval Criteria [1,2,3,4]

Coverage is provided in the following conditions:

- Patient 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**
- 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 poorly controlled diabetes; **AND**
- Must be used as single agent therapy and Tepezza cannot be used for retreatment**; AND**
- Patient's dose does not exceed 10 mg/kg intravenously initially, then 20 mg/kg IV every three weeks

Thyroid Eye Disease (TED) †

- 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

Effective date: 8/1/2020
Last Reviewed: 07/27/2020, 06/24/2021, 5/5/2022, 7/13/2023, 9/14/2023, 12/07/2023, 01/04/2024, 5/21/2025 Pharmacy Scope: Medicaid**(Pharmacy Benefit ONLY) Medical Scope: Commercial, Medicare Medicaid Plan (MMP)

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

IV. Renewal Criteria

Coverage cannot be renewed.

V. 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.

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, February 2025. Accessed May 2025.
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.

Neighborhood Health Plan

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)