Corporate Medical Policy: Treatment of Thyroid Eye Disease **"Notification"** **POLICY EFFECTIVE OCTOBER 1, 2026**

Restricted Product(s):

- teprotumumab-trbw (Tepezza®) intravenous infusion for administration by a healthcare professional
- veligrotug-vvze (Lumvoa®) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- For the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient has a diagnosis of **thyroid eye disease (TED)** related to Graves' disease (i.e., Graves' orbitopathy) **[medical record documentation required]**; **AND**
3. The patient has a diagnosis of moderate to severe disease, as defined by ONE of the following:
    a. The patient has active TED, indicated by a Clinical Activity Score (CAS) of 3 or greater in the more severely affected eye(s) or as scored by a comparable objective scoring system AND at least ONE of the following **[medical record documentation required]**:
        i. Lid retraction of ≥ 2 mm; **OR**
        ii. Moderate or severe soft-tissue involvement; **OR**
        iii. Proptosis of ≥ 3 mm above normal value for race and sex; **OR**
        iv. Periodic or constant diplopia; **OR**
    b. The patient has chronic TED with at least ONE of the following **[medical record documentation required]**:
        i. ≥3 mm increase in proptosis from before diagnosis of TED; **OR**
        ii. Proptosis ≥3 mm above normal value for race and sex; **AND**
4. The patient is euthyroid OR has mild hypo- or hyperthyroidism (i.e., free thyroxine [FT4] and free triiodothyronine [FT3] levels less than 50% above or below normal limits) **[medical record documentation required]**; **AND**
5. The patient has NOT had prior surgical treatment or orbital irradiation for TED **[medical record documentation required]**; **AND**
6. The patient is NOT planning on surgical treatment or orbital irradiation for TED during treatment with the requested agent **[medical record documentation required]**; **AND**

7. The patient has tried and had an inadequate response to corticosteroids used in the treatment of TED (e.g., prednisone, methylprednisolone, dexamethasone) **[medical record documentation required]**; **OR**
8. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL corticosteroids used in the treatment of TED **[medical record documentation required]**; **AND**
9. The patient has NOT had a decrease in best corrected visual acuity due to optic neuropathy within the previous 6 months (i.e., a decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement) **[medical record documentation required]**; **AND**
10. The patient does NOT have corneal decompensation that is unresponsive to medical management **[medical record documentation required]**; **AND**
11. If the request is for Tepezza:
    - **a.** The patient has NOT received previous treatment with veligrotug-vvze (Lumvoa) **[medical record documentation required]**; **AND**
    - b. ONE of the following **[medical record documentation required]**:
        - i. The patient has NOT previously received treatment with the requested agent in their lifetime; **OR**
        - ii. The patient is currently receiving treatment with the requested agent; **AND**
    - c. The patient will NOT be using the requested agent beyond one treatment course of 8 infusions during their lifetime **[medical record documentation required]**; **AND**
12. If the request is for Lumvoa:
    - **a.** The patient has NOT received previous treatment with teprotumumab-trbw (Tepezza) **[medical record documentation required]**; **AND**
    - b. ONE of the following **[medical record documentation required]**; **AND**
        - i. The patient has NOT previously received treatment with the requested agent in their lifetime; **OR**
        - ii. The patient is currently receiving treatment with the requested agent; **AND**
    - c. The patient will NOT be using the requested agent beyond one treatment course of 5 infusions during their lifetime **[medical record documentation required]**; **AND**
13. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, ophthalmologist) or has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
14. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 180 days (one treatment course per lifetime)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
teprotumumab-trbw (Tepezza®) intravenous (IV) infusion	TED in patients ≥18 years old	IV: 10 mg/kg initial infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions (total of 8 infusions)	J3241	1,500 (one treatment course of 8 infusions per lifetime)
veligrotug-vvze (Lumvoa®) intravenous (IV) infusion	TED in patients ≥18 years old	IV: 10 mg/kg every three weeks for a total of 5 infusions	C9399** J3490** J3590**	5,000 (one treatment course of 5 infusions per lifetime)

***Maximum units allowed for duration of approval**
****Non-specific assigned HCPCS codes, must submit requested product NDC**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    f. Re-initiation of therapy, defined as ONE of the following:

   i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
   ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
 g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Burch HB, 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*. 2022;32(12):1439-1470.
2. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the treatment of active thyroid eye disease. *N Engl J Med*. 2020;382:341-52.
3. 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.
4. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for thyroid-associated ophthalmopathy. *N Engl J Med*. 2017;376(18):1748-61.
5. Wang Y, Smith TJ. Current concepts in the molecular pathogenesis of thyroid-associated ophthalmopathy. *Invest Ophthalmol Vis Sci*. 2014;55(3):1735-48.
6. Patel Jain A, Cockerham K, Abrams J, et al. OR31-07 THRIVE-2 phase 3 trial of veligrotug (VRDN-001) in chronic thyroid eye disease (TED): efficacy and safety at 15 weeks. *J Endocr Soc*. 2025;9(Suppl 1):bvaf149.2240. doi:10.1210/jendso/bvaf149.2240.
7. Yen MT, Cockerham K, Saeed P, et al. THRIVE: A phase 3, randomized, double-masked, placebo-controlled study of veligrotug for active thyroid eye disease. *Ophthalmology*. 2026. doi:10.1016/j.ophtha.2026.04.022.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

July 2026: Criteria change (Tepezza): For Tepezza, added medical record documentation requirements to demonstrate that the patient has not received prior treatment with Tepezza during their lifetime or is currently receiving treatment, and will not receive more than one treatment course of 8 infusions per lifetime. **Policy notification given 8/3/2026 for effective date 10/1/2026**.
July 2026: Criteria change (Lumvoa, Tepezza): Added newly approved Lumvoa to the policy with associated criteria for treatment of thyroid eye disease (TED) regardless of TED activity or duration; added dosing and HCPCS codes C9399, J3490, and J3590 to the FDA label reference table. Updated the diagnostic requirements to distinguish active TED from chronic TED. Specified that a CAS of 3 or greater is

required in the more severely affected eye(s) or as scored by a comparable objective scoring system, with at least one additional finding consistent with moderate to severe disease is specific to active TED. Added option of either a ≥3 mm increase in proptosis from before diagnosis of TED or proptosis ≥3 mm above normal value for race and sex for diagnosis of chronic TED. For Tepezza, added that the patient must not have received previous treatment with Lumvoa. Clarified that the patient must not have previously received the requested agent in their lifetime or must currently be receiving treatment; and added additional clarification that use is limited to one treatment course of 8 infusions per lifetime with no change to intent. Added the one treatment course per lifetime verbiage to the FDA label reference table for clarity.
November 2025: Criteria change: Updated Site of Care medical necessity criteria to add additional bypass for patients with a history of severe adverse events or conditions that cause an increased risk for severe adverse event to align with the Place of Service for Medical Infusions policy for clarity of intent.
July 2023: Criteria change: Added newly updated FDA labeled indication to include thyroid eye disease regardless of thyroid eye disease activity or duration. Removed 'active' from diagnostic criteria. Updated Clinical Activity Score (CAS) requirement to 3 or greater. Updated maximum units according to coding unit definition for clarity. Minor adjustments made to formatting and reference added.
October 2021: Criteria change: Added Site of Care medical necessity criteria. **Policy notification given 8/2/2021 for effective date 10/1/2021**.
June 2021: Criteria change: Added diagnosis confirmation criteria for active, moderate to severe TED related to Graves' disease; added maximum units; medical policy formatting change. **Policy notification given 4/16/2021 for effective date 6/16/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.