teprotumumab-trbw (Tepezza)

Medical Benefit Drug Policy

Place of Service

Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: OPHTHALMIC AGENTS
Mechanism of Action: Insulin-like growth factor receptor (IGF-R) inhibitor
HCPCS:
J3241:Injection, teprotumumab-trbw, 10 mg
How Supplied:
500 mg lyophilized powder (single-dose vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Thyroid Eye Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Thyroid Eye Disease
Meets medical necessity if all the following are met:
Initial
1. Prescribed by or in consultation with an endocrinologist or ophthalmologist
2. Documentation that patient's thyroxine and free triiodothyronine levels are less than 50% above or below normal limits

Reauthorization
1. Prescribed by or in consultation with an endocrinologist or ophthalmologist

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2. Documentation that patient's thyroxine and free triiodothyronine levels are less than 50% above or below normal limits
3. One of the following (a or b):
   a. Patient experienced an inadequate response to first treatment course with Tepezza (proptosis reduction of <2 mm)
   b. Patient experienced a relapse following treatment with Tepezza (e.g. increase in proptosis increase in clinical activity score [CAS])

Covered Doses:
Up to 10 mg/kg given intravenously for the first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions (total treatment course = 8 infusions)

Coverage Period:
Initial: one treatment course (8 infusions over approximately six months)
Reauthorization: one treatment course

ICD-10:
E05.00, H05.831, H05.832, H05.833, H05.839

References

1. AHFS. Available by subscription at http://www.lexi.com
2. 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. Eur Thyroid J 2022; 11: e220189.
3. Douglas RS, Kahaly GJ, Ugradar S, et al. Teprotumumab efficacy, safety, and durability in longer-duration thyroid eye disease and re-treatment: OPTIC-X study. Ophthalmology 2022; 129:438-449.
4. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
5. Tepezza (teprotumumab) [prescribing information]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; November 2025.

Review History

Date of Last Annual Review: 3Q2026
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee