teprotumumab-trbw (Tepezza)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Infusion Administration (Prior authorization required)

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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first infusion of Tepezza or is being re-initiated on Tepezza after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Tepezza based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Tepezza based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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

Thyroid Eye Disease

Meets medical necessity if all the following are met:

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

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 authorization: One treatment course (8 infusions over approximately six months)

Reauthorization allowed for one additional course if meets all the following below:

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
3. One of the following:
   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])

ICD-10:
E05.00

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-trbw) Prescribing information. Horizon Therapeutics USA, Inc.; Deerfield, IL: 11/2024.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- No clinical change following annual review.

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