Teprotumumab-trbw (Tepezza®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Infusion Administration* [*Prior authorization required – see section (1)] HCPCS: **J3241** per 10 mg

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

- Thyroid eye disease

AHFS therapeutic class: Insulin-like growth factor receptor (IGF-R), inhibitors

Mechanism of action: Insulin-like growth factor receptor (IGF-R) inhibitor

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION **

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract),** 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.

ADMINISTRATION OF TEPEZZA 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for teprotumumab-trbw (Tepezza®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Thyroid eye disease

1. Prescribed by or in consultation with an endocrinologist or ophthalmologist, **AND**
2. Documentation that patient's thyroxine and free triiodothyronine levels are less than 50% above or below normal limits

Covered Dose

Up to 10 mg/kg for first IV infusion, followed by 20 mg/kg IV 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 if meets below: One treatment course (8 infusions over approximately six months)

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

ICD-10: E05.00 [Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm]

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for teprotumumab-trbw (Tepezza®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 500 mg lyophilized powder (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- 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.

- 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.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Tepezza® (teprotumumab-trbw) [Prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; 10/2021.

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- Section (2): Thyroid eye disease -
    - Removed management for active, progressive disease

      Rationale: In April 2023, FDA expanded the indication of Tepezza for use in thyroid eye disease regardless of disease activity or duration
    - Add coverage for retreatment

      Rationale: 2022 American Thyroid Association/European Tyroid Association Consensus Statement Recommendations

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee