

Tepezza (teprotumumab-trbw)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

Thyroid Eye Disease (TED) is also known as Graves' ophthalmopathy, Graves' orbitopathy, thyroid-associated ophthalmopathy, and thyroid orbitopathy. TED is an autoimmune condition most commonly associated with Graves' disease (hyperthyroidism). TED can occasionally present in euthyroid or hypothyroid patients, including those with Hashimoto's thyroiditis.

In TED, an abnormal immune response targets the thyroid gland and the tissues surrounding the eyes. Clinical manifestations include periorbital edema, lid retraction, proptosis, diplopia, corneal breakdown, and optic nerve compression. Blindness can occur due to complications of TED such as dysthyroid optic neuropathy (DON) or corneal breakdown.

Risk factors for TED include older age, male sex, genetic factors, cigarette smoking, thyroid dysfunction, and use of radioactive iodine.

Tepezza (teprotumumab-trbw) is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease.

Definitions

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Euthyroid" means normal thyroid gland function.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the applicant does not qualify.

"Proptosis" is the amount of protrusion of the eye from the orbital rim.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Tepezza (teprotumumab-trbw) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an ophthalmologist, neuro-ophthalmology, endocrinologist, or a physician who specializes in thyroid eye disease (TED); *AND*
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of Graves' disease with associated TED; *AND*
4. The member will NOT be using Tepezza (teprotumumab-trbw) in combination with another biologic immunomodulator [e.g., rituximab (Rituxan, Ruxience, Truxima), Actemra (tocilizumab), Kevzara (sarilumab)]; *AND*
5. The member meets ALL of the following:
 - a. No evidence of the member requiring surgical ophthalmological intervention; *and*
 - b. No evidence of having corneal decompensation that is unresponsive to medical management; *and*
 - c. No evidence of uncontrolled diabetes; *AND*
6. Tepezza (teprotumumab-trbw) is being prescribed at a dose and frequency that is within FDA approved labeling defined as ALL of the following:
 - a. The member has NOT received ≥ 8 Tepezza infusions (including the initial 10 mg/kg first infusion); *and*
 - b. IF the member has started therapy but has not completed eight (8) doses, approve the number of doses required for the patient to receive a total of 8 doses if medically necessary criteria are met; *and*
 - c. The dose does not exceed a single 10 mg/kg dose followed by seven (7) 20 mg/kg infusions given every 3 weeks; *AND*
7. The member meets the applicable [Medical Necessity Criteria for Initial Clinical Review](#) or [Subsequent Clinical Review](#) listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Thyroid Eye Disease (TED)

The Plan considers Tepezza (teprotumumab-trbw) medically necessary when ALL of the following criteria are met:

8. The member meets the above [General Medical Necessity Criteria](#); *AND*
9. There is documentation of ALL of the following:

- a. The member has active TED with a clinical activity score (CAS) of ≥ 4 (see [Appendix A](#));
and
 - b. The member has moderate-to-severe disease (see [Appendix B](#)); *AND*
10. The member's baseline proptosis measurement (in mm) prior to treatment is provided; *AND*
11. The member meets ONE of the following (see [Appendix C](#)):
- a. Euthyroid; *or*
 - b. Mild hypothyroidism or hyperthyroidism defined as free thyroxine (FT₄) and free triiodothyronine (FT₃) levels less than 50% above or below the normal limits of which efforts have been made to correct the mild hypo- or hyperthyroidism).
12. The member is unable to use, or has tried and failed ONE of the following (see [Appendix D](#))^[s]:
- a. Intravenous methylprednisolone; *or*
 - b. IF unable to use an intravenous method, oral prednisone.

If the above prior authorization criteria are met, the requested product will be authorized for up to 8 total lifetime infusions with an approval duration of up to 6-months.^[s]

Continued Care

[Medical Necessity Criteria for Subsequent Clinical Review](#)

Subsequent Indication-Specific Criteria

Thyroid Eye Disease (TED)

The Plan considers Tepezza (teprotumumab-trbw) medically necessary when ALL of the following criteria are met:

1. The member meets the above applicable [General Medical Necessity Criteria](#); *AND*
2. The member has experienced a documented improvement defined as meeting ONE of the following:
 - a. Reduction in proptosis ≥ 2 mm; *or*
 - b. Reduction in CAS from baseline of ≥ 2 points.
3. There is no evidence of unacceptable toxicity or adverse reactions to Tepezza (teprotumumab-trbw).

If the above reauthorization criteria are met, the requested product will be authorized for up to 8 total lifetime infusions with an approval duration of up to 6-months.^[s]

[Experimental or Investigational or unproven](#)^[s]

Tepezza (teprotumumab-trbw) for any other indication or use is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Hashimoto's Disease as clinical trials did not study in this population.

- The standard course of treatment is limited to a maximum of eight (8) doses. Requests for treatment continuation beyond eight (8) doses will be reviewed on a case-by-case basis. The open-label clinical extension study (OPTIC-X) was limited by a very small re-treatment population (five nonresponding patients and eight patients who initially responded and had subsequent flares). Therefore, safety and efficacy beyond eight (8) doses is uncertain. Candidates for continued treatment may include those with chronic TED who are still experiencing significant proptosis.

Applicable Billing Codes

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
J3241	Injection, teprotumumab-trbw, 10 mg

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
<i>Code</i>	<i>Description</i>
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm

References

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7. 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; 26:1343.
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9. Tepezza (teprotumumab) [prescribing information]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; November 2025.
10. UpToDate. Laboratory assessment of thyroid function. <https://www.uptodate.com/contents/laboratory-assessment-of-thyroid-function>. Accessed October 31, 2025.
11. UpToDate. Treatment of thyroid eye disease <https://www.uptodate.com/contents/treatment-of-thyroid-eye-disease>. Accessed October 31, 2025.

Appendix A

The Graves' orbitopathy CAS elements below are each assigned a score of 1. Graves' orbitopathy is considered active in patients with a CAS of ≥ 3 . The pivotal clinical trials (NCT01868997 and NCT03298867) evaluating Tepezza (teprotumumab) enrolled individuals with a CAS of ≥ 4 .

1. Painful feeling behind the globe over last four weeks
2. Pain with eye movement during last four weeks
3. Redness of the eyelids
4. Redness of the conjunctiva
5. Swelling of the eyelids
6. Chemosis (edema of the conjunctiva)
7. Swollen caruncle (flesh body at medial angle of eye)
8. Increase in proptosis ≥ 2 mm
9. Decreased eye movements $\geq 5^\circ$ any direction
10. Decreased visual acuity ≥ 1 line on Snellen chart

Appendix B

TED Disease Severity Assessment

- Mild disease, at least one of the following:
 - Minor lid retraction (< 2 mm); *or*
 - Mild soft-tissue involvement; *or*
 - Exophthalmos < 3 mm above normal for race and gender; *or*
 - No or intermittent diplopia; *or*
 - Corneal exposure responsive to lubricants.
- Moderate-to-severe disease, at least one of the following:
 - Lid retraction ≥ 2 mm; *or*
 - Moderate or severe soft-tissue involvement; *or*
 - Exophthalmos ≥ 3 mm above normal for race and gender; *or*
 - Inconstant or constant diplopia.
- Sight-threatening disease, at least one of the following:
 - Dysthyroid optic neuropathy (DON); *or*
 - Corneal breakdown.

Appendix C

Typical reference ranges of thyroid gland function for healthy adults are:

- thyroid-stimulating hormone (TSH) 0.4 to 4.0 mU/l
- free thyroxine (FT₄) 4.6 to 11.2 mcg/dL OR 9.0 to 25.0 pmol/l
- triiodothyronine (T₃) 75 to 195 ng/dL
- free triiodothyronine (FT₃) 3.5 to 7.8 pmol/l

Appendix D

Table 3: Systemic Corticosteroids for TED and Dosing

Systemic Corticosteroid for TED	Dosing
Intravenous methylprednisolone (IVMP)	Cumulative doses of 4.5 g (4500 mg) over 3 months <ul style="list-style-type: none">• 0.5 g weekly (500 mg) for 6 weeks followed by 0.25 g (250 mg) weekly for an additional 6 weeks Cumulative dose of IVMP >8.0 g (8000 mg) should be avoided
Oral prednisone	30 to 100 mg/day

Clinical Guideline Revision / History Information

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