DR.009.E TEPEZZA® (teprotumumab-trbw)

Original Implementation Date :11/01/2020
Version [E]Date : 07/15/2026
PARP Approved Date: 06/24/2026
Last Reviewed Date: 07/15/2026

Thank you for being a valued provider for members in one or more of our health plans: Jefferson Health Plans Medicare Advantage, Jefferson Health Plans Individual and Family Plans, Jefferson Health Plans CHIP, and/or Jefferson Health Plans EverWell (our Medicaid plan).

PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans lines of business.

POLICY STATEMENT

TEPEZZA® is considered Medically Necessary for the treatment of Thyroid Eye Disease when the criteria listed in this policy are met.

FDA APPROVED INDICATIONS

TEPEZZA® is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.

OFF-LABEL USE

Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the Medical Staff will be predicated on the appropriateness of treatment and full consideration of medical necessity.

For off-label use, Medical Directors will review scientific literature and local practice patterns.

PRIOR AUTHORIZATION CRITERIA

INITIAL CRITERIA

*AUTHORIZATION DURATION: IF **ALL CRITERIA MET**, APPROVE FOR 6 MONTHS (MAX 8 TOTAL INFUSIONS)*

1. Adults 18 years of age and older; **AND**
2. Patient has moderate to severe Thyroid Eye Disease confirmed by at least ONE of the following:
    - Lid retraction of greater than or equal to 2 mm.
    - Moderate or severe soft-tissue involvement.
    - Proptosis of greater than or equal to 3 mm above the normal values for race and sex.
    - Periodic or constant diplopia.
3. Patient does not have poorly controlled diabetes; **AND**
4. Medication is being prescribed by or in consultation with a specialist (endocrinologist, ophthalmologist, or ocular surgeon specializing in treatment of thyroid eye disease); **AND**

The patient will not exceed a one-time treatment course of 8 infusions given once every 3 weeks (10mg/kg on first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions.) Renewal Criteria.

Authorization Duration: Coverage cannot be renewed.

DOSAGE AND ADMINISTRATION

See package labeling.

RISK FACTORS/SIDE EFFECTS

See package labeling.

MONITORING

- Monitor patients for signs and symptoms of inflammatory bowel disease (IBD), including patients without a history of IBD; discontinue TEPEZZA® if IBD exacerbation is suspected.
- Monitor glucose levels in all patients prior to infusion and continue to monitor while on treatment; ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving TEPEZZA®.
- Monitor patient's hearing before, during, and after treatment; consider benefit-risk of treatment with patients.
- Monitor for infusion reactions, interrupt or slow the rate of infusion and use appropriate medical management if an infusion reaction occurs.
- TEPEZZA® (teprotumumab) is contraindicated during pregnancy; if patient becomes pregnant during treatment, TEPEZZA® should be discontinued, and the patient should be advised of the potential risk to the fetus.

CLINICAL EVIDENCE

Teprotumumab (an insulin-like growth factor 1 [IGF-1] receptor inhibitor) was approved for the treatment of Graves' orbitopathy by the US Food and Drug Administration (FDA) in 2020, based on the findings from two 24-week trials comparing teprotumumab with placebo in 171 patients with active, moderate-to-severe orbitopathy. In each trial, a greater proportion of patients in the teprotumumab group had a reduction in clinical activity score and degree of proptosis (69 versus 20 percent with placebo and 78 versus 7 percent with placebo, respectively). The durability of efficacy requires confirmation with long-term follow-up studies. Eye symptoms in the patients in the trial had to have begun within nine months of trial entry, and it is unclear whether the drug would be as effective in patients whose disease was of longer duration. In addition, there was no comparison with the effectiveness of glucocorticoids, the standard therapy for patients with moderate-to-severe orbitopathy.

CODING

Note: *The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using*

the code that was in effect on the date the service was rendered. This list may not be all inclusive.

CPT® is a registered trademark of the American Medical Association.

CPT Code	Description
N/A	N/A

HCPCS Code	Description
J3241	Injection, teprotumumab-trbw, 10 mg

ICD 10 Codes	Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
E05.01	Thyrotoxicosis with diffuse goiter with thyrotoxic crisis or storm
E05.10	Thyrotoxicosis with toxic single thyroid nodule without thyrotoxic crisis or storm
E05.20	Thyrotoxicosis with toxic multinodular goiter without thyrotoxic crisis or storm
E05.30	Thyrotoxicosis from ectopic thyroid tissue without thyrotoxic crisis or storm
E05.80	Other thyrotoxicosis without thyrotoxic crisis or storm
E05.90	Thyrotoxicosis, unspecified without thyrotoxic crisis or storm
H05.89	Other disorders of orbit

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making. Policy Bulletins are

developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Policy Bulletin may be updated and therefore is subject to change.

For Jefferson Health Plans EverWell and Jefferson Health Plans CHIP products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
2026 Annual review. Revisions to Prior authorization criteria, Dosage & administration, Risk Factors /Side Effects and Monitoring Sections. Code removed from coding section. References updated.	E	07/15/2026
2025 Annual review. Prior Authorization Criteria and Monitoring section updated. ICD 10 diagnosis codes added. References updated.	D	07/16/2025
2024 annual review. Risk factors/Side effects section was updated.	C	09/18/2024
2023 Annual policy review. Reference section was updated. FDA Approved Indications updated	B	09/01/2023
2022 Annual policy review. Reference section was updated.	A	11/01/2020
2021 Annual policy review. Code J3241 was added to the coding. Codes C9061, J3490, J3590 were removed.	A	11/01/2020
New Drug Policy	A	11/01/2020

REFERENCES

1. Tepezza® [package insert]. Dublin, Ireland; Horizon Therapeutics Ireland, DAC, January 2020. Updated November 2025. Accessed May 2026.

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3. Douglas RS, Kahaly GJ, Patel A, Sile S, Thompson EHZ, Perdok R, Fleming JC, Fowler BT, Marcocci C, Marinò M, Antonelli A, Dailey R, Harris GJ, Eckstein A, Schiffman J, Tang R, Nelson C, Salvi M, Wester S, Sherman JW, Vescio T, Holt RJ, Smith TJ. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020 Jan 23;382(4):341-352. doi: 10.1056/NEJMoa1910434.

4. 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.

5. Terry F. Davies, Henry B. Barch, UpToDate , last update **Aug 06, 2024.** Clinical features and diagnosis of Graves' orbithopthy (ophthalmopathy).

6. Terry F. Davies, Henry B. Barch, UpToDate, last update : **Apr 29, 2026**. Treatment of thyroid eye disease

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