

## Medical Policy:

### Tepezza (teprotumumab-trbw)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.213	February 11, 2025	May 18, 2020

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Tepezza (teprotumumab-trbw) is a fully human immunoglobulin G1 monoclonal antibody that binds to IGF-1R, which is overexpressed in the orbital connective tissues of patients with thyroid eye disease and blocks its activation and signaling.

## Length of Authorization

Coverage will be provided for 6 months (max total of 8 infusions) and may NOT be renewed.

## Dosing Limits

### Max Units (per dose and over time) [HCPCS Unit]:

- 115 billable units initially followed by 230 billable units every 3 weeks thereafter for a total of 8 doses

## Guideline

### I. Initial Approval Criteria

1. **Thyroid Eye disease** (aka Graves' ophthalmopathy, Graves' orbitopathy, thyroid-associated ophthalmopathy, and thyroid orbitopathy).
  - A. The patient is  $\geq 18$  years of age; **AND**
  - B. According to the prescriber, the patient has been assessed as having active disease; **AND**
    - i. Patient had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids; **OR**
  - C. Patient has inactive disease; **AND**
  - D. Patient has not had a decrease in best corrected visual acuity (BCVA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement); **AND**
  - E. Patient is euthyroid [*Note: mild hypo- or hyperthyroidism is permitted which is defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits (every effort should be made to correct the mild hypo- or hyperthyroidism promptly)*]; **AND**
  - F. Patient does not have corneal decompensation that is unresponsive to medical management; **AND**
  - G. Patient does not have uncontrolled diabetes; **AND**
  - H. Patient hearing will be assessed before, during, and after treatment; **AND**
  - I. Used as single agent therapy; **AND**
  - J. Tepezza is prescribed by, or in consultation with, an ophthalmologist, endocrinologist, oculoplastic surgery or neuro-ophthalmology, or physician who specializes in thyroid eye disease.

#### Limitations/Exclusions

1. Tepezza is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.
2. Tepezza will not be used in combination with another biologic immunomodulator [e.g., rituximab (Rituxan, Ruxience, Truxima), Actemra (tocilizumab), Kevzara (sarilumab)]
3. The continued use of Tepezza beyond 8 infusions in the patient's lifetime is unproven and not medically necessary.

#### Dosage/ Administration

Indication	Dose
Thyroid Eye Disease	10mg/kg for first infusion, followed by 20mg/kg every 3 weeks for 7 additional infusions

#### Applicable Procedure Codes

Code	Description
J3241	Injection, teprotumumab-trbw, 10 mg. J-Code effective date: 10/01/2020

#### Applicable NDCs

Code	Description
75987-130-15	Tepezza (teprotumumab) 500mg single-dose vial

#### ICD-10 Diagnoses

Code	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
E05.11	Thyrotoxicosis with toxic single thyroid nodule with thyrotoxic crisis or storm
E05.20	Thyrotoxicosis with toxic multinodular goiter without thyrotoxic crisis or storm
E05.21	Thyrotoxicosis with toxic multinodular goiter with thyrotoxic crisis or storm
E05.30	Thyrotoxicosis from ectopic thyroid tissue without thyrotoxic crisis or storm
E05.31	Thyrotoxicosis from ectopic thyroid tissue with thyrotoxic crisis or storm
E05.40	Thyrotoxicosis factitia without thyrotoxic crisis or storm
E05.41	Thyrotoxicosis factitia with thyrotoxic crisis or storm
E05.80	Other thyrotoxicosis without thyrotoxic crisis or storm
E05.81	Other thyrotoxicosis with thyrotoxic crisis or storm
E05.90	Thyrotoxicosis, unspecified without thyrotoxic crisis or storm
E05.91	Thyrotoxicosis, unspecified with thyrotoxic crisis or storm

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	02/11/2025	Annual Review: Initial Criteria: <u>Thyroid Eye disease</u> . Removed: “of at least moderate severity based on signs and symptoms (e.g. the degree of inflammation, degree of proptosis, presentation of diplopia, etc.” from the following statement: “According to the prescriber, the patient has been assessed as having active disease of at least moderate severity based on signs and symptoms (e.g. the degree of inflammation, degree of proptosis, presentation of diplopia, etc.)” Added: “Patient has not had a decrease in best corrected visual acuity (BCVA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement); AND Patient is euthyroid [Note: mild hypo- or hyperthyroidism is permitted which is defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits (every effort should be made to correct the mild hypo- or hyperthyroidism promptly)]; AND Patient does not have corneal decompensation that is unresponsive to medical management; AND Patient does not have uncontrolled diabetes; AND Patient hearing will be assessed before, during, and after treatment; AND Used as single agent therapy; AND” Added the following prescribers to the list: “oculoplastic surgery or neuro-ophthalmology,”
EmblemHealth & ConnectiCare	1/22/2024	Annual Review: Updated length of authorization and dosage limits, Initial Criteria: Added: “Patient had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids; OR Patient has inactive disease; AND”
EmblemHealth & ConnectiCare	4/18/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	1/13/2023	Transfer to New Template, strikethrough code C9061, deleted 9/30/20
EmblemHealth & ConnectiCare	9/11/2020	Added J-Code (J3241) Injection, teprotumumab-trbw, 10 mg. J-Code effective date: 10/01/2020
EmblemHealth & ConnectiCare	9/11/2020	Added C-Code (C9061) Injection, teprotumumab-trbw, 10 mg. C-Code effective date: 07/01/2020

EmblemHealth & ConnectiCare	05/18/20	New medical policy
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## References

1. Tepezza injection [prescribing information]. Lake Forest, IL: Horizon Therapeutics; January 2020.
2. *Tepezza Billing and Coding Guide*. Horizon Patient Services. 2020. [www.hzndocs.com/TEPEZZA-Billing-and-Coding-Guide.pdf](http://www.hzndocs.com/TEPEZZA-Billing-and-Coding-Guide.pdf). Accessed 18 May 2020.
3. GDIT. "Teprotumumab-Trbw for Injection, for Intravenous Use (Tepezza) HCPCS Code J3590: Billing Guidelines." *NC Medicaid Division of Health Benefits*. 07 April 2020. <https://medicaid.ncdhhs.gov/blog/2020/04/07/teprotumumab-trbw-injection-intravenous-use-tepezza%E2%84%A2-hcpcs-code-j3590-billing>. Accessed 18 May 2020.