Medical Policy:
Tepezza (teprotumumab-trbw)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.213	January 22, 2024	May 18, 2020

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 ≥ 18 years of age; **AND**
   B. 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.); **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. Tepezza is prescribed by, or in consultation with, an ophthalmologist, endocrinologist, 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	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

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. 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.