Medical Policy

Tepezza ® (teprotumumab-trbw)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_025
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Tepezza ® (teprotumumab-trbw) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Tepezza will be provided for a total of 8 doses and cannot be renewed.
Dosing Limitation: 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for 7 additional infusions.

A. Patient is 18 years of age or older; **AND**
B. Tepezza is prescribed by, or in consultation with, an ophthalmologist, endocrinologist, or physician who specializes in thyroid eye disease; **AND**

C. Patient has NOT had a decrease in best corrected visual acuity (BVCA) 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**
D. 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**
E. Patient has a clinical diagnosis of Thyroid Eye Disease (TED) that is related to Graves' Disease (i.e., Graves' orbitopathy); **AND**
F. Patient has a baseline clinical activity score (CAS) of at least 4; **AND**
G. Patient has active phase TED that is non-sight threatening but has a significant impact on daily living (e.g., lid retraction ≥ 2 mm, moderate or severe soft tissue involvement, exophthalmos ≥ 3 mm above normal for race and gender, and/or inconstant or constant diplopia); **AND**
H. Patient's onset of TED symptoms occurred within the previous 9 months; **AND**
I. Patient had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

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.

DEFINITIONS

1. TEPEZZA (teprotumumab-trbw) for injection, for intravenous use. Initial U.S. Approval: 2020
    a. TEPEZZA (teprotumumab-trbw) for injection is a sterile, preservative-free, white to off-white lyophilized powder.

CODING

Applicable NDC Codes	
75987-0130-15	Tepezza (teprotumumab) 500mg single-dose vial

Applicable Procedure Code	
J3241	Injection, teprotumumab-trbw, 10 mg.

Applicable ICD-10 Codes

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

EVIDENCE BASED REFERENCES

1. Product Information: TEPEZZA(TM) intravenous injection, teprotumumab-trbw intravenous injection. Horizon Therapeutics USA Inc (per manufacturer), Lake Forest, IL, 2020.

POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	February 2, 2022 – Annual Review and approval (no policy revisions made) February 28, 2023 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	2/2/2022