Teprotumumab-trbw (Tepezza®)

NDC CODE(S) 75987-0130-xx TEPEZZA 500MG Solution Reconstituted (HORIZON THERAPEUTICS USA, INC)

DESCRIPTION

Teprotumumab-trbw, an insulin-like growth factor-1 receptor inhibitor (IGF-1R), is a fully human IgG1 monoclonal antibody produced in Chinese hamster ovary (CHO-DG44) cells. Teprotumumab-trbw's mechanism of action in individuals with Thyroid Eye Disease has not been fully characterized. Teprotumumab-trbw binds to IGF-1R and blocks its activation and signaling.

POLICY

- Teprotumumab-trbw for the treatment of Thyroid Eye Disease is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Teprotumumab-trbw for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age; **AND**

Universal Criteria
- 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**
- 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 poorly controlled diabetes; **AND**
- Must be used as single agent therapy**; AND**

Thyroid Eye Disease (TED)
- Patient has a clinical diagnosis of TED that is related to Graves' disease (i.e., Graves' orbitopathy); **AND**
- Individual has a baseline clinical activity score (CAS) of at least 4 §; **AND**
- 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**
- Patient must have active disease (this may include, but is not limited to, the following: onset of TED symptoms within the previous 9 months); **AND**
- Patient had an inadequate response, or there is a contraindication or intolerance, to high dose intravenous glucocorticoids

§ Assessment of Thyroid Eye Disease (TED): Clinical Activity Score (CAS) Elements
- Painful feeling behind the globe over last four weeks

− Pain with eye movement during last four weeks − Redness of the eyelids − Redness of the conjunctiva − Swelling of the eyelids − Chemosis (edema of the conjunctiva) − Swollen caruncle (flesh body at medial angle of eye) − Increase in proptosis ≥2 mm* − Decreased eye movements ≥5° any direction* − Decreased visual acuity ≥1 line on Snellen chart*
*Note: Each element is assigned a score of one. Elements denoted with a * can be used when a previous assessment is available. A seven-point scale is used when prior assessment is not available.*

RENEWAL CRITERIA

Coverage cannot be renewed.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Thyroid Eye Disease	Administer 10 mg/kg intravenously initially, then 20 mg/kg intravenously every three weeks for 7 additional infusions (8 infusions total). Administer the diluted solution intravenously over 90 minutes for the first two infusions. If well tolerated, the minimum time for subsequent infusions can be reduced to 60 minutes. If not well tolerated, the minimum time for subsequent infusions should remain at 90 minutes.

LENGTH OF AUTHORIZATION

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

DOSAGE 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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health

plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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11. Lexi-Comp Online. (2020, March). AHFS DI. *Teprotumumab-trbw*. Retrieved January 21, 2021 from Lexi-Comp Online with AHFS.
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EFFECTIVE DATE 6/2/2021

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