curative

TITLE:	TEPEZZA INFUSION POLICY
POLICY #:	MM-PNP-047
VERSION #:	01
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	4/11/2024
CURRENT REVISION DATE:	N/A

1. PURPOSE

This policy will be used to inform medical necessity decisions related to authorization requests for Tepezza Infusion.

This policy supports medical necessity review for teprotumumab-trbw (Tepezza™).

Receipt of sample product does not satisfy any criteria requirements for coverage

2. SCOPE

Medical UM Department

3. DEFINITIONS

Tepezza, an insulin-like growth factor-1 receptor (IGF-1R) antagonist, is indicated for the treatment of thyroid eye disease, regardless of thyroid eye disease activity or duration.

4. OVERVIEW

Disease Overview

- Thyroid eye disease is a progressive, vision-threatening autoimmune inflammatory disease of the eye and orbital tissues with predominant features of fibrosis and adipogenesis.4 It is also recognized in literature as Graves 'ophthalmopathy, Graves' orbitopathy, thyroid-associated ophthalmopathy, and thyroid orbitopathy.
- Thyroid eye disease is mostly related to Graves' disease. It can also develop in patients with other thyroid diseases (e.g., Hashimoto's thyroiditis) and has a higher prevalence in women than men (16 per 100,000 vs. 3 per 100,000, respectively).5 In active disease, orbital fibroblasts appear responsible for soft tissue enlargement by expressing potential pathogenic autoantigens, such as thyrotropin receptor and IGF-1R.4
- Activation of orbital fibroblasts leads to increased hyaluronic acid production, proinflammatory cytokine synthesis, and enhanced differentiation into either myofibroblasts or adipocytes. These processes result in inflammation, enlargement of extraocular muscles and expansion of orbital tissue and fat, which in turn cause forward displacement of the eye, resulting in proptosis and inflammation.6 The degree of severity can be staged as mild, moderate-to-severe, or sight-threatening, following quantitative assessment of lid aperture width, proptosis measurement, diplopia score, degrees of abduction in eye muscle movement, examination of the cornea for evidence of exposure keratitis or ulceration, and assessment of optic nerve function.

5. RESPONSIBILITIES

6. POLICY

Medical Necessity

Documentation: Submission of ***all*** the following information is necessary to initiate the prior authorization review: Supporting chart notes or medical record indicating moderate-to-severe disease as applicable to criteria for initial approval.

This medication ***must*** be prescribed by or in consultation with an ophthalmologist.

Criteria for Initial Approval:

Teprotumumab-trbw (Tepezza) may be considered medically necessary when **ALL** of the following criteria are met:

- The Individual is 18 years of age or older; **and**
- Diagnosis of Graves' disease associated with active thyroid eye disease (TED) with a Clinical Activity Score (CAS) ≥ 4 in the most severely affected eye; **and**
- Presence of moderately to severely active TED, associated with at least one of the following:
    - Lid retraction ≥ 2 mm
    - Moderate or severe soft tissue involvement
    - Exophthalmos ≥ 3 mm above normal for race and gender
    - Diplopia **and**
- History of intolerance, failure, or contraindication to oral or intravenous glucocorticoids (e.g., prednisone, methylprednisolone) **and**
- One of the following:
    - Patient is euthyroid [defined as free triiodothyronine (T3) and thyroxine (T4) levels within the normal limits]; **or**
    - Presence of mild hypo- or hyperthyroidism [defined as free T3 and T4 levels less than 50% above or below the normal limits] **and**
- The patient is undergoing treatment to correct the mild hypo- or hyperthyroidism to maintain a euthyroid state ; **and**
- The Individual does not require immediate surgical ophthalmological intervention; **and**
- The Individual does not have clinically significant optic neuropathy (Individual has not had a decrease in best corrected visual acuity (BVCA) within the previous six (6) months, i.e., decrease in vision of two (2) lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement); **and**
- The Individual does not have corneal decompensation unresponsive to medical management; **and**
- The Individual is euthyroid, mild hypothyroid, mild hyperthyroid (defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50 percent above or below the normal limits) or seeking care for dysthyroid state from an endocrinologist or other provider experienced in the treatment of thyroid diseases; **and**

- If an individual is diabetic, the individual is being managed by an endocrinologist or other provider experienced in the treatment and stabilization of diabetes; **and**
- The Individual is not pregnant; **and**
- Other conservative measures have been tried and failed e.g. for mild TED; artificial tear drops will help with dry eye relief. Selenium supplements can also be beneficial. For severe TED, steroids and/or orbital radiotherapy may be considered. Required to be documented with length of treatment.
- The authorization period is for one (1) course of therapy only.

Reauthorization Criteria

- More than one (1) course of therapy of eight (8) infusions of teprotumumab-trbw (Tepezza) is considered experimental/investigational. Scientific evidence does not support more than one (1) course of therapy of eight (8) infusions.

Exclusions

- The use of teprotumumab-trbw (Tepezza) for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

Contraindication for Tepezza

Infusion Reactions: TEPEZZA may cause infusion reactions for individuals with

- Preexisting Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD).
- Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA.

Reauthorization Criteria

Exclusions: Coverage will not be provided for repeat series of Tepezza infusions.

- More than one (1) course of therapy of eight (8) infusions of teprotumumab-trbw (Tepezza) is considered experimental/investigational. Scientific evidence does not support more than one (1) course of therapy of eight (8) infusions. The continued use of Tepezza beyond 8 infusions in the patient's lifetime is unproven and not medically necessary.
- The use of teprotumumab-trbw (Tepezza) for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

Notes: Disease Severity Assessment

1. Mild disease, at least one of the following:
   - Minor lid retraction (<2 mm)
   - Mild soft-tissue involvement
   - Exophthalmos <3 mm above normal for race and gender
   - No or intermittent diplopia.

- Corneal exposure responsive to lubricants

2. Moderate-to-severe disease, at least one of the following:

- Lid retraction ≥2 mm
- Moderate or severe soft-tissue involvement
- Exophthalmos ≥3 mm above normal for race and gender
- Inconstant or constant diplopia

3. Sight-threatening disease, at least one of the following:

- Dysthyroid optic neuropathy (DON)
- Corneal breakdown

Approval Duration and Quantity Restrictions: Approval: 6 months Initial infusion to be done at hospital facility. Transitioning to Quantify on the 2nd treatment. 1st infusions happen in a hospital facility to monitor patient response to the medication.

7. PROCEDURE

N/A

8. TRAINING REQUIREMENT

8.1. All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

9. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

10. DOCUMENTATION

Ordering Physician must submit ***all*** documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

11. REFERENCE DOCUMENTS AND MATERIALS

11.1. Regulatory Authority - N/A

12. COLLABORATING DEPARTMENTS

N/A

13. DOCUMENT CONTROL

APPROVED BY:	
Charles,Brandon 4/11/2024	DocuSigned by: Charles,Brandon DE2813BF834C49A...
(Printed Name) (Date)	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A:

N/A