Tepezza (teprotumumab-trbw)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Tepezza drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Tepezza (teprotumumab-trbw) is indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Supporting chart notes or medical records indicating clinical activity score (CAS) and moderate-to-severe disease and thyroid testing results

Criteria for Initial Approval

I. Tepezza (teprotumumab-trbw) may be considered **medically necessary** for the treatment of thyroid eye disease (TED) when ALL of the following criteria are met:

   - Member is 18 years of age or older
   - Medication is prescribed by or in consultation with a specialist in the treatment of Graves' disease associated with TED (e.g., endocrinologist, ophthalmologist)
   - Member has active disease with a CAS greater than or equal to 4 (See Appendix A)

- Member has moderate-to-severe disease (See Appendix B)
- Member has experienced an inadequate response to glucocorticoids at a maximally tolerated dose, unless member has a documented intolerance, FDA labeled contraindication, or hypersensitivity: OR member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and is experiencing a positive therapeutic outcome
- Member is euthyroid prior to initiating therapy
- Member is not currently pregnant and does not plan to become pregnant during treatment or within 6 months of the last treatment

Approval will be for **6 months and will be limited to one course of treatment (up to 8 infusions) per lifetime.**

APPENDICES

Appendix A: TED Activity Assessment – CAS Elements

Elements*	**Score**
Painful feeling behind the globe over last 4 weeks	1
Pain with eye movement during last 4 weeks	1
Redness of the eyelids	1
Redness of the conjunctiva	1
Swelling of the eyelids	1
Chemosis (edema of the conjunctiva)	1
Swollen caruncle (flesh body at medial angle of eye)	1

*A 7-point scale with 1-point given for each element present

Appendix B: Disease Severity Assessment

1. Mild disease, at least one of the following:
    a. Minor lid retraction (<2 mm)
    b. Mild soft-tissue involvement
    c. Exophthalmos <3 mm above normal for race and gender
    d. No or intermittent diplopia
    e. Corneal exposure responsive to lubricants
2. Moderate-to-severe disease, at least one of the following:
    a. Lid retraction ≥2 mm
    b. Moderate or severe soft-tissue involvement
    c. Exophthalmos ≥3 mm above normal for race and gender
    d. Inconstant or constant diplopia
3. Sight-threatening disease, at least one of the following:
    a. Dysthyroid optic neuropathy (DON)
    b. Corneal breakdown

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9061 Injection, teprotumumab-trbw, 10 mg (deleted 09-30-2020)
- J3241 Injection, teprotumumab-trbw, 10 mg (effective 10-01-2020)

APPENDICES

- Tepezza [package insert]. Deerfield, IL: Horizon Therapeutics USA Inc; July 2023.
- Bartalena L, Baldeschi L, Kostas B, et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of Graves' orbitopathy. *Eur J Endocrinol. 2021;185(4):G43-G67.*.
- Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. *Thyroid*. 2016;26(10):1343-1421.
- Burch HB, Perros P, Bednarczuk T, Cooper DS, et al. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association. *Thyroid*. 2022 Dec;32(12):1439-1470.
- ClinicalTrials.gov [Internet]. Bethesda, MD: National Library of Medicine. 2023 March 16 NCT04583735, *A Study Evaluating TEPEZZA® Treatment in Patients with Chronic (Inactive) Thyroid Eye Disease*; Accessed 2023 April 23

POLICY HISTORY

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