CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs

Tepezza™ (teprotumumab-trbw)

Effective: September 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Tepezza was based on the OPTIC trial. In this trial, adults with Graves' disease and active moderate to severe thyroid eye disease were randomized to receive Tepezza or placebo every 3 weeks for 8 doses. There was a significantly higher proptosis responder rate at Week 24 in patients treated with Tepezza compared to placebo.

Food and Drug Administration (FDA) Approved Indications:

Tepezza (teprotumumab-trbw) is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease (TED).

The recommended dose of Tepezza is an intravenous infusion of 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for seven (7) additional infusions.

Clinical Guideline Coverage Criteria

The Plan may cover Tepezza for Members when the following clinical criteria are met:

1. A documented diagnosis of Graves' disease

AND

2. Documentation of active thyroid eye disease

AND

3. Prescribed by or in consultation with an ophthalmologist or endocrinologist

AND

4. Member is at least 18 years of age

Limitations

- Continuation of Tepezza beyond eight infusions is considered experimental/investigational and not medically necessary.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3241	INJECTION TEPROTUMUMAB-TRBW 10 MG

References:

1. Tepezza (teprotumumab-trbw) [package insert]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; October 2021.
2. Ross 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.
3. Douglas RS, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Eng J Med. 2020 Jan;382:341-52.
4. Smith TJ, et al. Teprotumumab for Thyroid-Association Ophthalmopathy. New Engl J Med. 2017;376:1748-61.
5. Wang Y, et al. Thyroid Eye Disease: How a Novel Therapy May Change the Treatment Paradigm. Ther. Clin. Risk Manag. 2019;15:1305-18.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC).
June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T), effective September 1, 2023.
Subsequent endorsement date(s) and changes made:

- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.