MVP Health Care Medical Policy

Medicare Part B: Tepezza (teprotumumab-trbw)

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
Related Policies:	**N/A**

Drugs Requiring Prior Authorization under the medical benefit

J3241 TEPEZZA (teprotumumab-trbw) injection, 500 mg powder vials for solution

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under Part D benefit.

Overview

TEPEZZA (teprotumumab-trbw) is a fully human monoclonal antibody IV infusion indicated for the treatment of thyroid eye disease (TED). Thyroid eye disease, also known as Grave's ophthalmopathy, is an inflammatory condition primarily impacting the extraocular muscles (the muscles that move the eye) and the orbit (bone cavity in the skull that holds the eyeball). The disease course transitions from an active progressive period characterized by inflammation to a stable and fibrotic (inactive) period. Diagnosis is made based on clinical signs and symptoms including feeling irritation/grittiness in the eyes, red or inflamed conjunctiva, excessive tearing or dry eyes, eyelid swelling, light sensitivity, diplopia (double vision), and proptosis (bulging or displacement of the eyes). The pathogenesis of thyroid eye disease is incompletely understood at this time which has resulted in inconsistently effective treatment of the disease and uncertain modification of the disease outcome itself. Such treatments have included high-dose corticosteroids and radiotherapy of the eye. In many members with thyroid eye disease, radiotherapy and glucocorticoids result in dose-limiting adverse effects and minimal improvement in proptosis. Unlike these other methods of treating thyroid eye disease,

TEPEZZA is an insulin-like growth factor 1 receptor (IGF-1R) antagonist, blocking its activation and signaling therefore working to attenuate the underlying autoimmune processes involved in ophthalmopathy. IGF-1R has roles in the body in development, metabolism, and immune processes and strong evidence has implicated the IGF-1R in the pathogenesis of TED. In multiple placebo-controlled randomized control trials, TEPEZZZA improved both diplopia and proptosis in members with active moderate-severe thyroid eye disease at 24 weeks. It also improves the signs and symptoms of Thyroid Eye Disease including eye pain, redness, and swelling.

Indications/Criteria

TEPEZZA may be considered for coverage when the following criteria are met:

- Member is at least 18 years of age
- Documented diagnosis of Graves' eye disease, also called Graves' Ophthalmopathy or Thyroid Eye disease
- Member must be euthyroid or with mild hypothyroidism or hyperthyroidism, defined as free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below the normal limits for the testing laboratory
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology
- For female members, healthcare provider has documented the member is not pregnant and that highly effective contraceptive methods have been implemented prior to, during, and for 6 months after treatment has been discussed with the member.
- For members with pre-existing diabetes, documentation that diabetes is under appropriate glycemic control due to increased risk of hyperglycemia.

Initial Approval for 24 weeks (8 infusions administered every 3 weeks).

Continuation of TEPEZZA beyond 8 infusions is and will be reviewed on a case-by-case basis.

Exclusions

- Prior surgical treatment for Thyroid Eye Disease

- Age, dose, frequency of dosing and/or duration of therapy outside of FDA approved labeling.

References

1. Tepezza injection [prescribing information]. Lake Forest, IL: Horizon Therapeutics;July 2023..

2. Smith TJ, Kahaly GL, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy [internet]. NEJM; 2017 [cited 2021 Aug 23]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1614949

3. Douglas R, Kahaly GL, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease [internet]. NEJM; 2020 [cited 2021 Aug 24]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1910434