Teprotumumab (TEPEZZA)
Criteria for Use
April 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive teprotumumab

- ☐ Urgent surgical ophthalmological intervention needed (e.g., compressive optic neuropathy, severe exposure keratopathy, etc.)
- ☐ Pregnant or planning to become pregnant during treatment or for 6 months following treatment

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Restricted to VA/VA Community Care provider who is a neuro-ophthalmologist or ophthalmologist with oculoplastic training (generally co-managed with an endocrinologist)
- ☐ Diagnosis of Graves' disease
- ☐ Active thyroid eye disease with Clinical Activity Score of 4 or greater^1
- ☐ Moderate-severe thyroid eye disease with at least ONE of the following: lid retraction ≥ 2mm, moderate or severe soft-tissue involvement, proptosis ≥3 mm above normal for race and sex, periodic or constant diplopia

Additional Inclusion Criteria

- ☐ For patients who can become pregnant: Implement effective contraception methods prior to initiation and continue for at least 6 months after stopping treatment. Discontinue teprotumumab if patient becomes pregnant during therapy
- ☐ For patients with partners who can become pregnant: A barrier contraceptive should be used during treatment and for 6 months after treatment (unless surgically sterile)

1. **Clinical Activity Score (CAS)** One point is given for the presence of each of the parameters assessed: Spontaneous retrobulbar pain; pain on attempted upward or downward gaze; redness of eyelids, redness of conjunctiva; swelling of caruncle or plica; swelling of eyelids; swelling of conjunctiva (chemosis)

Notes:

- In the clinical trials, hyperglycemia was reported in 10% of patients receiving teprotumumab. Monitor patients with diabetes or pre-diabetes for hyperglycemia during the course of treatment
- For patients who are not euthyroid, continued attention should be given to correct hypo- or hyperthyroidism
- Smoking is a well-known risk factor for the progression of thyroid eye disease and more severe disease. Smoking cessation should be addressed for those who are smoking
- There are insufficient data to support retreatment after a full 8 infusion course at this time. Subsequent courses would have to be adjudicated locally on a case by case basis

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