SmartHealth

Ascension

Teprotumumab

(Tepezza®) J3241

Covered with prior authorization

Teprotumumab (Tepezza®) may be authorized when the following criteria are met:

- Confirmed Moderate to Severe Thyroid Eye Disease defined by at least one of the following:
  - Lid retraction ≥ 2 mm; **OR**
  - Moderate or severe soft tissue involvement; **OR**
  - Exophthalmos ≥ 3 mm above normal for race and gender; **OR**
  - Diplopia; **AND**
- Patient must be
  - Euthyroid with thyroid function under control; **OR**
  - With mild hypothyroidism undergoing treatment to correct; **OR**
  - With mild hyperthyroidism undergoing treatment to correct; **AND**
- Restricted to ophthalmologists and endocrinologists; **AND**
- Patient is ≥ 18 years of age; **AND**
- Dosing regimen is limited to total of 8 doses per lifetime
  - Initial: 10 mg/kg (actual body weight) IV infusion x 1 dose; **AND**
  - Maintenance: 20 mg/kg (actual body weight) IV infusion every 3 weeks for 7 additional doses

Exclusion criteria:

- Patients < 18 years of age;
- Pregnant or lactating patients;
- Tepezza® will not be used in combination with another biologic immunomodulator;
- Doses exceeding 8 per lifetime;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization for approved indications is up to 8 doses.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Clinical documentation provided must be from within the most recent 12 months.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

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

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

References:

Ascension. (2022, February). *Teprotumumab Criteria for Use for SmartHealth*. Ascension TAG INITIATIVES - PSWP.

Douglas, R. (2020). Teprotumumab for the Treatment of Active Thyroid Disease. *N Engl J Med*, *382*, 341-352. https://www.nejm.org/doi/full/10.1056/nejmoa1910434

Tepezza® (Teprotumumab) label. (2020, January). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761143s000lbl.pdf

Tepezza® (teprotumumab-trbw) Prescribing Information. Horizon Therapeutics Dublin, Ireland 2022. Accessed January 10, 2022

Criteria History/ Revision Information:

Date	Summary of Changes
Feb 2022	Developed and Approved by Ascension Infusion Expert Review Panel
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.