Tepezza (teprotumumab-trbw)

Override(s)	Approval Duration
Prior Authorization	*One course of treatment; defined as a total of 8 intravenous infusions of Tepezza (teprotumumab-trbw) administered every 3 weeks

Medications	Dosing Limit
Tepezza (teprotumumab-trbw) 500 mg vial	**Initial dose**: One 10 mg/kg infusion **Subsequent doses**: 20mg/kg every 3 weeks for seven infusions

APPROVAL CRITERIA

Requests for one course* of Tepezza (teprotumumab-trbw) may be approved if the following criteria are met (Douglas 2020):

I. Individual has a diagnosis of Thyroid Eye Disease; **AND**
II. Documentation is provided that individual has symptomatic moderate to severe disease, as defined by one or more of the following:
    A. Lid retraction ≥ 2 mm; **OR**
    B. Moderate or severe soft tissue involvement**; OR**
    C. Proptosis ≥ 3 mm above normal for race and gender; **OR**
    D. Intermittent or constant diplopia; **AND**
III. Documentation is provided that individual has a clinical activity score (CAS) greater than or equal to 4 in the more severely affected eye; **AND**
IV. Documentation is provided that one of the following applies:
    A. Thyroid function tests are provided and are within normal limits as defined by laboratory standard (i.e. individual is euthyroid); **OR**
    B. Thyroid function tests show free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below normal limits as defined by laboratory standard.

Tepezza (teprotumumab-trbw) may not be approved for the following:

I. More than one course* of treatment; **OR**
II. Individual has had prior orbital irradiation or eye surgery for TED; **OR**
III. Individual has decreased best-corrected visual acuity due to optic neuropathy as defined by decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect; **OR**
IV. Individual has unresponsive corneal decompensation; **OR**
V. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 7, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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; 26:1343-1421. Erratum in: *Thyroid.* 2017 Nov;27(11):1462
6. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. *N Engl J Med.* 2017; 376: 1748-1761.
7. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. *N Engl J Med.* 2020; 382: 341-352.
8. Douglas RS, Kahaly GJ, Ugradar S, et al. Teprotumumab Efficacy, Safety, and Durability in Longer-Duration Thyroid Eye Disease and Re-treatment: OPTIC-X Study. *Ophthalmology*. 2022;129(4):438-449. doi:10.1016/j.ophtha.2021.10.017
9. Bartalena L, Kahaly G, Baldeschi L, et al. The 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy. European Journal of Endocrinology. 2021; 185(4), G43-G67.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.