HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Tepezza (teprotumumab-trbw)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Tepezza is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease (TED), also known as Graves' orbitopathy (GO). It binds to IGF-1R and blocks its activation and signaling. Tepezza was the first drug approved by the FDA for TED, approved in 2020.
Hyperthyroidism of autoimmune origin is referred to as Graves' disease. TED occurs in some of these patients, causing inflammation and tissue expansion behind the eye leading to proptosis (bulging eyes), often accompanied by diplopia. Most cases are classified as mild; however, blindness is possible in severe cases. The mainstay medical therapy for moderate to severe TED is glucocorticoids.

Tepezza (teprotumumab-trbw) will be considered for coverage when the following criteria are met:

Thyroid Eye Disease (TED)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist or endocrinologist; AND
3. Member has a documented diagnosis of moderate to severe thyroid eye disease (TED) with at least one of the following:
   a) Proptosis ≥3 mm above normal for race and gender
   b) Moderate or severe soft tissue involvement
   c) Diplopia
   d) Orbital pain and/or pressure
   e) Lid retraction ≥2 mm; AND
4. Chart notes must show the member is euthyroid or mildly hypo- or hyper-thyroid (defined as having free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the reference normal limits) prior to starting therapy; AND
5. Member does NOT have sight-threatening TED such as severe optic neuropathy or corneal breakdown.
6. **Dosage allowed/Quantity limit:** 10mg/kg initial dose intravenously followed by seven 20mg/kg infusions every 3 weeks (total of 8 infusions).

If all the above requirements are met, the medication will be approved for 24 weeks.

For **reauthorization**: Retreatment will not be authorized due to a lack of robust literature available to support the use of Tepezza beyond 24 weeks.

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HAP CareSource considers Tepezza (teprotumumab-trbw) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/22/2020	New policy for Tepezza created.
02/24/2022	Transferred to new template. Updated references. Added definition of moderate to severe disease, made CAS a separate point. Added endocrine as a specialist. Removed “high dose” from steroid trial; regimen may vary.
04/20/2023	Updated references. Updated policy to allow treatment of TED regardless of disease activity or duration (per phase 4 study and label update); previously only allowed for active disease. Removed CAS score requirement, added exclusion of sight-threatening TED, added orbital pain/pressure as qualifier, removed steroid trial.

References:

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11. Douglas RS, Kossler AL, Abrams J, et al. Expert Consensus on the Use of Teprotumumab for the Management of Thyroid Eye Disease Using a Modified-Delphi Approach. *J Neuroophthalmol*. 2022;42(3):334-339. doi:10.1097/WNO.0000000000001560
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