AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Tepezza® (teprotumumab-trbw) (J3241) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

- ❑ IV: 10 mg/kg as a single dose, followed by 20 mg/kg every 3 weeks for 7 additional doses
- ❑ Maximum 6-month authorization and maximum of 8 infusions
- ❑ NDC: 75987-0130-15; 500 mg vial (1 each) = 50 billable units

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Warnings and Precautions:

- Tepezza may cause severe hearing problems including hearing loss, which in some cases may be permanent. Tell your doctor if you have any signs or symptoms of hearing problems or changes in hearing.
- For patients with inflammatory bowel disease (IBD), such as Crohn's disease or ulcerative colitis, Tepezza may make your IBD symptoms worse.

Part A:

- Globe protrusion: 13.9 mm in Asian males, 16.5 mm in white males, 18.5 mm in African American males. Adult females have lower exophthalmometry readings than adult males with an average of 15.4 mm in white women and 17.8 mm in African American women

Provider Please Note: The use of teprotumumab (Tepezza) does **NOT** meet the definition of medical necessity for the treatment of inactive TED (CAS ≤ 2) due to insufficient evidence in peer-reviewed medical literature and guidelines to support safety, efficacy and net health outcomes.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Authorization Criteria: 6 months (Maximum of 8 doses per lifetime)

- ❑ Member is ≥18 years of age
- ❑ Prescriber is a specialist in ophthalmology, endocrinology, oculoplastic surgery or neuro-ophthalmology
- ❑ Member has a clinical diagnosis of Thyroid Eye Disease (TED) that is related to Graves' Orbitopathy
- ❑ Provider has submitted documentation to support member has **ONE** of the following:
  - ❑ Lid retraction of ≥ 2 mm
  - ❑ Proptosis of ≥ 3 mm above the normal values for race and sex (see Part A)
  - ❑ Exophthalmometer ≥ 20 mm
- ❑ Symptoms began within 12 months of the date of prior authorization form submission
- ❑ Member has a Clinical Activity Score of at least ≥ 4 **(please complete table below)**:

Parameters Assessed	Spontaneous retrobulbar pain	Pain on attempted upward or downward gaze	Eyelid erythema	Eyelid edema	Conjunctival hyperaemia	Conjunctival chemosis	Inflammation of caruncle or plica
Score: Present=1 or Absent=0							
Total:							

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- ❑ Member is **NOT** currently smoking and has not smoked within the last 30 days
- ❑ If member has diabetes, disease must be adequately controlled (HbA1c <9%) and prescriber must attest to monitoring glycemic levels prior to starting Tepezza®
- ❑ Member must have tried and failed 6 weeks of intravenous methylprednisolone at dose of ≥ 500 mg/week. Please provide medication start date: _____
- ❑ Member must have been compliantly taking thyroid medication for the last 3 months and must be euthyroid **OR** has lab levels within the following ranges **(must submit labs completed within the last 30 days)**:
  - ❑ Free triiodothyronine (FT3): 3.5-6.5 pmol/L **OR** 230-619 pg/dL
  - ❑ Free Thyroxine (FT4): 11.5-22.7 pmol/L **OR** 0.7-1.9 ng/dL
  - ❑ Thyrotropin (TSH): 0.55-4.78 mIU/L **OR** 0.5-6 µIU/mL
- ❑ Requested dosing is in accordance with the United States Food and Drug Administration and medication will be prescribed for a maximum of 8 doses per lifetime

Reauthorization: NOT COVERED. The clinical benefit of Tepezza has not been demonstrated beyond 8 infusions in phase 3 clinical trials. The continued use of Tepezza beyond 8 infusions in the patient's lifetime is unproven and not medically necessary.

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*