

RX.PA.064.MPC Tepezza[®] (teprotumumab-trbw)

The purpose of this policy is to define the prior authorization process for Tepezza[®] (teprotumumab-trbw).

Tepezza[®] (teprotumumab-trbw) is indicated for the treatment of thyroid eye disease

The drug, **Tepezza[®] (teprotumumab-trbw)**, is subject to the prior authorization process.

PROCEDURE

1. Thyroid Eye Disease (TED)

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be 18 years of age or older
- Must have a documented diagnosis of Grave's disease
- Documentation of clinical activity score (CAS) of ≥ 4
 - Pain
 - Pain/pressure in a periorbital or retroorbital distribution
 - Pain on attempted up, side or down gaze during the last 4 weeks
 - Redness
 - Redness of eyelids
 - Redness of conjunctiva
 - Swelling
 - Swelling of eyelids
 - Chemosis
 - Inflammation of caruncle or plica
 - Increase in measured proptosis ≥ 2 mm assessed over 3 months
 - Impaired function
 - Decrease in eye movement $\geq 8^\circ$ assessed over 3 months
 - Decrease in visual acuity (2 Snellen chart lines) assessed over 3 months
- Documentation of at least one of the following (labs must be within 2 months):
 - Member is euthyroid
 - Member has mild hypo or hyperthyroidism (free thyroxine (FT4) and free triiodothyronine (FT3) levels $<50\%$ above or below the normal limit
- Documentation of intolerance, contraindication to or failed treatment with glucocorticoid therapy for at least 4 weeks

- Diabetic members must not have poorly controlled diabetes (HbA1c >9%) and are monitoring glycemic levels prior to starting Tepezza
- Must be prescribed by an ophthalmologist or endocrinologist
- Member has not had previous surgical intervention of TED

B. Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Tepezza will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member’s condition has improved or stabilized based upon the prescriber’s assessment while on therapy
- Member must have documentation of a reduction in CAS from baseline of ≥ 2 points
- Member must have documentation of a reduction in proptosis ≥ 2 mm
- Must be prescribed by an ophthalmologist or endocrinologist
- Member does not require surgical intervention of TED

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC) and have been taking Tepezza have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).; AND
- Provider has a documented clinical response of the member’s condition which has stabilized or improved based upon the prescriber’s assessment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	3 months
Reauthorization	1 year

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

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HCPCS Code(s):

Code	Description
J3241	Injection, teprotumumab-trbw, 10 mg
C9061	Injection, teprotumumab-trbw, 10 mg

REFERENCES

1. Tepezza (teprotumumab-trbw) [prescribing information]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; Jan 2020.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/2026</i>
<i>Annual Review</i>	<i>02/2025</i>
<i>Annual policy review. Update to reauthorization criteria for non-MPC renewals</i>	<i>02/2024</i>
<i>New Policy</i>	<i>10/2022</i>