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Next Review Due By: 10/2026
Policy Number: C18462-A

Tepezza (teprotumumab-trbw)

PRODUCTS AFFECTED

Tepezza (teprotumumab-trbw)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Thyroid eye disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. THYROID EYE DISEASE:
1. Documented diagnosis of Graves' disease with active thyroid eye disease (TED) (also known as Graves' Ophthalmopathy, Graves' Orbitopathy and Thyroid- Associated Ophthalmopathy (TAO))

[DOCUMENTATION REQUIRED]
AND

2. Documentation of proptosis ≥ 3mm increase from member's baseline (before diagnosis of TED) as estimated by treating physician and/or proptosis ≥ 3mm above normal for race and gender
AND
3. Member has not received 8 or more Tepezza infusions (including the initial 10 mg/kg first infusion)
AND
4. Documentation of ONE of the following:
    a. Member's thyroid level has been normalized prior to initiation of treatment, OR
    b. Member is euthyroid or mildly hypo/hyper-thyroid with a free thyroxine (FT4) and free triiodothyronine (FT3) levels <50% above or below the normal limits

AND
5. Prescriber attests, or clinical reviewer has found, member does not have ANY of the following:
    a. Previous orbital irradiation or surgery for TED
    b. Does not require immediate surgical ophthalmological intervention or have planned surgery/irradiation during course of treatment
    c. Biopsy-proven or clinically suspected inflammatory bowel disease (IBD)
    d. Poorly controlled diabetes
    NOTE: Members with pre-existing diabetes should be under appropriate glycemic control before receiving teprotumumab

AND
6. Documentation of an inadequate response (2 month trial), serious side effects, or contraindication to one systemic corticosteroid up to maximally indicated doses
NOTE: Systemic corticosteroids (not an all-inclusive list; may require PA): Prednisone: 30 mg/day PO; Methylprednisolone: 500 mg IV once weekly for weeks 1 to 6, then 250 mg IV once weekly for weeks 7-12
Molina Reviewer Note: Glucocorticoids remain standard immunomodulatory therapy for moderate-to- severe Graves' orbitopathy (Davies TF, 2020; AAO, 2025). Although worsening orbitopathy may respond favorably and rapidly to oral prednisone therapy via its anti-inflammatory and immunosuppressive actions, IV glucocorticoid pulse therapy has become widely used for more severe orbitopathy and has the advantage of fewer side effects than high oral doses of prednisone. However, very high IV doses (cumulative doses greater than 8 g) have been seen to induce liver failure and must be avoided (EUGOGO 2021).

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified specialist in ophthalmology, endocrinology, oculoplastic surgery or neuro-ophthalmology. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Initial: 10 mg/kg as a single dose
Maintenance: 20 mg/kg IV infusion every 3 weeks for 7 additional infusions (8 infusions total including initial dosage)

Maximum Quantity Limits – Dose does not exceed a single 10 mg/kg dose followed by seven 20 mg/kg infusions given every 3 weeks (8 infusions total)

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Tepezza (teprotumumab-trbw). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Insulin-Like Growth Factor-1 Receptor Inhibitors (IGF-1R)

FDA-APPROVED USES:
Indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
APPENDIX 1: Thyroid Eye Disease (TED)
Thyroid Eye Disease (TED) also referred to as Graves' Ophthalmopathy, Graves' Orbitopathy and Thyroid-Associated Ophthalmopathy (TAO)

- An immune-mediated inflammatory disorder often associated with orbital inflammation, fibrosis, and fat expansion and produces expansion of the extraocular muscles and fat in the orbit. Characterized by enlargement of the extraocular muscles as well as an increase in the orbital fat volume. While symptoms are typically bilateral, they are often asymmetric. The most common presenting signs are orbital and periorbital edema, eyelid retraction, eyelid lag in downgaze, restrictive strabismus, compressive optic neuropathy, and exposure keratopathy with common symptoms of ocular irritation and dryness (Douglas RS, 2011).
- Most commonly associated with Graves' hyperthyroidism but can also occur in association with other thyroid states, hypothyroid and euthyroid states. Approximately 40% of individuals with Graves' disease develop TED; smokers are particularly at risk for developing this disorder (Patel et al., 2019). The condition is seen in individuals with no other evidence of thyroid dysfunction, and occasionally in patients who have Hashimoto's Disease. However, most thyroid patients will not develop thyroid eye disease, and if so, only mildly so.
- The disease course of TED does not always coincide with thyroid activity or the treatment of underlying thyroid dysfunction, therefore the treatment of thyroid dysfunction does not necessarily affect course of Grave's ophthalmopathy (American Academy of Ophthalmology, 2019). The exact underlying etiology of TED is not yet completely understood; however, the presumed mechanism is related to autoimmune activation of orbital fibroblasts by Graves' disease-related autoantibodies (Mohyi and Smith, 2018).

- The demographics of thyroid-associated orbitopathy reflects that of patients with thyroid disease and is, therefore, more frequently seen in women. Risk factors for TED include age, gender, ethnicity, and family history. A positive family history of TED is also noted in a large population of TED patients.
  The median age of diagnosis is 43 years for all patients, with a range from 8-88 years.
  Patients diagnosed over the age of 50 years have a worse prognosis overall.
- Many patients with TED present with a mild course of disease and can be treated symptomatically with supportive care and monitored for worsening. Moderate-to-severe TED, however, presents a therapeutic challenge since there have been no disease-modifying therapies available to reverse or reduce associated tissue damage and no FDA-approved agents indicated for the treatment TED (Hayes, 2020).
- The mainstay of treatment for patients with active, moderate-to-severe TED has been off-label glucocorticoids. Glucocorticoids have limited efficacy in TED with an estimated 50% of patients reporting inadequate symptom relief (Patel et al., 2019). In addition, glucocorticoids do not improve proptosis, a clinically significant symptom that can cause loss of sight (Douglas, 2019). Furthermore, lengthy use of steroid therapy has considerable side effects include increased risk of infection, worsening diabetes and/or hypertension, and weakening of bones.
- Patients with moderate-to-severe active disease may also receive immunosuppressive therapy aimed at reducing the inflammation. However, oral and intravenous steroids do not reverse the underlying pathophysiology and they may temporarily mask the symptoms of the disease without considerable effect on the disease progression including proptosis. Steroid sparing agents and human monoclonal antibodies approved for other inflammatory indications have been used in TED, but these agents have not demonstrated disease-modifying efficacy.
- Orbital radiotherapy or orbital decompression surgery may be required to treat patients whose vision is threatened.
- In the absence of effective pharmacotherapies, the only option left for patients is eventual surgery once the inflammatory process subsides. Pharmacotherapies targeting underlying pathogenic mechanisms for patients with active, moderate-to-severe TED had not been FDA approved prior to Tepezza.
- Tepezza provides an alternative nonsurgical treatment option that could potentially spare patients from multiple invasive surgeries

APPENDIX 2: Clinical Activity Score (CAS)

Disease activity can be assessed using the clinical assessment score (CAS). This set of clinical criteria was initially described in 1989 (Mourits et al. 1989) and has been widely used in assessing patients with TED and in planning their treatment. The criteria include seven clinical parameters of inflammation easily determined in the clinic. Furthermore, they include changes in three functional parameters over a period of 1–2 months.

For each criterion met by the patient, one point is assigned, with a total CAS of 10. Patients with a low score (<3) respond poorly to immunosuppressive therapy, indicating that they have passed the disease stage of active inflammation (Mourits et al. 1989). Other studies have confirmed the clinical value of the CAS in determining disease activity and the likelihood of a response to immunosuppressive therapy. One study found that a CAS of 4 or more has a positive predictive value for a treatment response with corticosteroids of 80% (Mourits et al. 1997)

Determining the Clinical Activity Score (CAS)

At the initial visit, patients are given a CAS score of 1-7 (one point for each of the following signs or symptoms)

- Spontaneous pain in or around the eye in the past 4 weeks (pain without eye movement)
- Eye pain associated with eye movement in the past 4 weeks
- Swelling of the eyelids
- Redness of eyelids
- Conjunctival injection (redness of the actual eyeball)
- Chemosis (swelling of the eyeball)
- Swelling of the caruncle (the red prominence at the inner corner of the eye)

At subsequent follow-up visits, the 3 following criteria are added for a potential CAS score of 10

- Increase in proptosis/exophthalmos (bulging of the eye out of the eye socket) of the eye (by at least 2mm)
- Decrease in motility of an eye in one direction (by at least 5º)
- Decrease in vision (by at least 1 line on the Snellen chart)

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Tepezza (teprotumumab-trbw) was granted FDA approval for the treatment of thyroid eye disease based on results from two 24-week trials, a Phase 2 clinical study and a Phase 3 confirmatory trial (OPTIC), comparing teprotumumab with placebo in 171 patients with active, moderate-to-severe Graves' orbitopathy. In both trials, a greater proportion of patients in the teprotumumab group had a reduction in clinical activity score and degree of proptosis. There are no controlled head-to-head trials with glucocorticoids, the standard therapy for moderate-to-severe orbitopathy; however, Tepezza, a disease- modifying treatment, has been shown to have greater effects on proptosis and diplopia than experience with glucocorticoids. Additionally, longer-term follow-up is being studied in ongoing open- label extension to determine the long-term benefit of Tepezza for the treatment of TED. Efficacy in patients who relapsed after initially responding to Tepezza is currently being evaluated in the OPTIC X trial.

Phase 3 OPTIC
Treatment of Graves' Orbitopathy [Thyroid Eye Disease] to Reduce Proptosis with Teprotumumab Infusions in a Randomized, Placebo-Controlled, Clinical Study) (Douglas et al., 2020)

A randomized double-masked placebo-controlled phase III multicenter trial evaluating Tepezza in adult participants with Graves' disease, who had active, moderate-to-severe thyroid eye disease, had ocular symptoms that began within 9 months before the baseline assessment, and had a
*Clinical Activity Score (CAS) of at least 4 in the more proptotic (study) eye. Participants were randomized to receive intravenous infusions of either Tepezza (n=41) (10 mg/kg for the first infusion and 20 mg/kg for subsequent infusions) or placebo (n=42) once every 3 weeks for 21 weeks for a total of 8 infusions; the last trial visit of the treatment period was at 24 weeks.

*The Clinical Activity Score is based on 7 components: spontaneous retrobulbar pain, pain on attempted eye movements, conjunctival redness, redness of the eyelids, chemosis, swelling of the caruncle or plica, and swelling of the eyelids. Each component is scored as present or absent (score of 1 or 0, respectively), and the Clinical Activity Score is given as the sum of the scores (range, 0 to 7, with higher scores indicating greater level of inflammation). Participants were required to be euthyroid, although mild hypothyroidism or hyperthyroidism was allowed at screening.

The primary outcome was a proptosis response (defined as a reduction in proptosis of ≥ 2 mm from baseline in the study eye without a corresponding increase of ≥ 2 mm in the fellow eye) at week 24. At week 24, the percentage of patients with a proptosis response was higher with Tepezza than with placebo (83% [34 patients] vs. 10% [4 patients], P<0.001).

Key secondary outcomes were a Clinical Activity Score of 0 or 1 at week 24, the mean change in proptosis across trial visits, a diplopia response at week 24, and the mean change in overall score on the Graves' ophthalmopathy-specific quality-of-life (GO-QOL) questionnaire across trial visits.
Outcomes were also evaluated in the contralateral eye. All secondary outcomes were significantly better in patients treated with Tepezza compared with placebo, including overall response (78% versus 7%), Clinical Activity Score of 0 or 1 (59% versus 21%), mean change in proptosis (−2.82 mm versus −0.54 mm), diplopia response (68% versus 29%), and the mean change in GO-QOL overall score (13.79 points vs. 4.43 points) (P≤0.001 for all comparisons).

Most adverse events were mild or moderate in severity; 2 serious events occurred in the Tepezza group, of which 1 (an infusion reaction) led to treatment discontinuation. Phase II RCT (Smith et. al., 2017) This double-blind trial randomized 88 adults in a 1:1 ratio to receive intravenous infusions of either Tepezza or placebo once every 3 weeks for 24 weeks (total of 8 infusions). Patients were stratified according to smoking status. All patients had active moderate-to-severe thyroid eye disease (TED), defined as a Clinical Activity Score (CAS) ≥ 4 in the more severely affected eye (study eye), and all were diagnosed ≤ 9 months after onset of TED symptoms. Enrollment criteria required euthyroid status; all patients had well-managed thyroid disease. The trial excluded patients with optic neuropathy, severe ocular surface erosion, and those who improved in CAS score ≥ 2 points between screening and baseline visit.

The primary outcome was a composite endpoint defined as a reduction in CAS of ≥ 2 points and a reduction in proptosis of ≥ 2 mm, as measured by Hertel exophthalmometer, in the study eye, in the absence of a corresponding amount of worsening in the non-study eye. This was assessed after 24 weeks of treatment in an intention-to-treat population of patients who received at least 1 infusion of Tepezza (n=42) or placebo (n=45.)

Secondary endpoints included CAS and proptosis severity measured separately as continuous variables over time, Graves' ophthalmopathy-specific quality-of-life (GO-QOL) score, and subjective diplopia assessment.

Despite stratification by smoking status, there were more smokers in the placebo group (n=18) than in the Tepezza group (n=11). Investigators used analytic methods when calculating P values to adjust for this imbalance. A statistically greater proportion of participants in the Tepezza group met the primary composite endpoint compared with placebo (69% versus 20%, respectively; P<0.001). At weeks 6, 12, 18, and 24, the reduction from baseline in proptosis and CAS statistically favored Tepezza over placebo (secondary outcomes). Of note, a reduction in proptosis of ≥ 4 mm was observed at week 24 in 40% of patients treated with Tepezza, while no patient in the placebo group achieved this outcome. Quality-of- life measures also statistically favored Tepezza over placebo, with the exception of the GO-QOL appearance subscale which did not statistically differ between the 2 groups.

Adverse events that occurred in > 5% of patients treated with Tepezza included nausea (19%), muscle spasms (19%), diarrhea (14%), hyperglycemia (12%), alopecia, dry skin, dysgeusia, headache, paresthesia, hearing impairment, and weight loss (7% for each event). A 48-week follow- up phase of this trial is ongoing to assess durability of treatment response.
Douglas (2019) reported that the proptosis outcome (≥ 2 mm reduction) was met in 71.4% of the Tepezza-treated patients as compared with 20% of the placebo-treated patients (P<0.001). The proptosis benefit was observed early in the trial (study week 6), and all individual patients demonstrated some benefit at week 24.

Confirmatory Trials
The OPTIC Phase 3 confirmatory clinical trial and the OPTIC-X open-label extension clinical trial to evaluate the long-term safety and efficacy of TEPEZZA in TED.

OPTIC 48-Week Follow-Up Period OPTIC (Treatment of Graves' Orbitopathy [Thyroid Eye Disease] to Reduce

Proptosis with Teprotumumab Infusions in a Randomized, Placebo- Controlled, Clinical Study)

Phase 3 confirmatory clinical trial (a multicenter, randomized, double-blind, placebo-controlled trial) included a 24-week treatment period and a 48-week off-treatment follow-up period. At the end of the 24- week treatment period, patients who were proptosis responders entered into the 48-week off- treatment follow-up period, without receiving additional TED treatment, including TEPEZZA. Clinic visits were scheduled for Weeks 28, 36, 48, 60, and 72 (Months 7, 9, 12, 15, and 18). Sustained proptosis response in the OPTIC 48-week off-treatment follow-up period was defined as a 2 mm or more proptosis improvement from OPTIC baseline at Week 24, a 2 mm or more proptosis improvement from OPTIC baseline at Week 72 and no additional TED treatment, including TEPEZZA.

OPTIC-X (Treatment of Graves' Orbitopathy [Thyroid Eye Disease] to Reduce Proptosis with Teprotumumab Infusions in an Open-Label Clinical Extension Study); (NCT03461211)

OPTIC-X was designed to evaluate whether certain patients may benefit from retreatment or longer treatment (more than 6 months) with TEPEZZA. OPTIC-X was a 48-week, open-label extension trial in which patients who participated in the OPTIC Phase 3 clinical trial received eight additional infusions of TEPEZZA (10 mg/kg for the first infusion followed by 20 mg/kg for the remaining seven infusions).

OPTIC-X evaluated the safety and efficacy of TEPEZZA in TED patients who were enrolled in OPTIC and were either proptosis *non-responders at Week 24 of OPTIC or were proptosis responders at Week 24 but †relapsed during the 48-week off-treatment follow-up period.

*Non-responders were defined as patients who did not achieve at least a 2 mm proptosis improvement from baseline at Week 24 of OPTIC.

†Relapse was defined as patients who lost at least 2 mm of their Week 24 proptosis improvement during the 48-week off-treatment follow-up period (even if their proptosis was still substantially better than at baseline of OPTIC) or who had a substantial increase in the number of inflammatory signs or symptoms without worsening proptosis. Patients could qualify as relapsing at any point during the 48-week off- treatment follow-up period of OPTIC.

The primary endpoint was proptosis responder rate, which is defined as the percentage of participants with a 2 mm or more proptosis reduction since baseline of OPTIC-X in the study eye without deterioration of proptosis in the fellow eye (2 mm or more increase) at Week 24. The estimated study completion date is March 2022.

Top-line Data from the Phase 3 OPTIC and OPTIC-X trials in TED (July 31, 2020; Horizon Therapeutics)

- In the OPTIC 48-week off-treatment follow-up period, the majority of TEPEZZA patients who were proptosis responders at Week 24 in OPTIC maintained their proptosis response at Week 72 (19/34; 56 percent) without receiving additional TED treatment. Of the 15 patients who did not qualify as maintaining a proptosis response, eight patients were at least 2 mm better than baseline at the time of their last assessment in the OPTIC 48-week off-treatment follow-up period. The 15 patients include four who prematurely discontinued the study, two who had worsened slightly but not enough to qualify as relapsed for OPTIC-X and nine who met the OPTIC-X criteria for relapse prior to Week 72 of the off-treatment follow-up period (eight of whom entered OPTIC-X for retreatment and one who did not enroll in OPTIC-X).
- Similar durability from Week 24 to Week 72 was demonstrated for other endpoints in the OPTIC 48-week off-treatment follow-up period, including diplopia and CAS.
- 89% of patients (33/37) who received placebo during the OPTIC trial and then entered OPTIC-X and received TEPEZZA achieved the primary endpoint of a 2 mm or more reduction in proptosis at Week 24 (average reduction of -3.5 mm). This is consistent with results from the OPTIC trial, where 83 percent of TEPEZZA patients (n=41) had a proptosis reduction of 2 mm or more at Week 24 (average reduction of -3.3 mm).
- The results for other OPTIC-X endpoints, including diplopia and Clinical Activity Score (CAS), are similar to what was observed in OPTIC.
- These patients who received placebo in OPTIC and their first course of TEPEZZA in OPTIC-X had a TED diagnosis for an average of one year and as long as 16 months, compared with an average of six months in the OPTIC trial.
- For relapsed patients who were retreated with an additional course of TEPEZZA, more than 60% had a 2

mm or more proptosis improvement from OPTIC-X baseline at Week 24.

- Only five patients had not achieved a proptosis response after completing a full course of TEPEZZA in OPTIC. Of these, two achieved a 2 mm or more proptosis reduction in OPTIC-X after an additional course of TEPEZZA.
- There were no new safety concerns in OPTIC-X or the OPTIC 48-week off-treatment follow-up period, including in patients who received additional TEPEZZA treatment.

Top-line Data from the Phase 4 Clinical Trials in Patients with Chronic/Low Clinical Activity Score (CAS) TED (April 10, 2023; Horizon Therapeutics)
The Phase 4 trial evaluated patients with an initial diagnosis of TED between two to 10 years (mean duration of 5.2 years; SD 1.77) and low levels of disease activity (mean CAS of 0.4; SD 0.49), whereas the prior pivotal trials (Phase 2 and 3) that formed the basis of the original FDA approval of TEPEZZA evaluated patients with disease duration of nine months or less and higher levels of disease activity. At Week 24, topline data per the pre-specified primary analysis method (intent-to-treat) demonstrated that the primary endpoint was met, and patients treated with TEPEZZA achieved a statistically significant reduction in proptosis from baseline compared to those receiving placebo. No new safety signals were observed. Based on the results of this trial, the FDA labeled indication has been updated to specify Tepezza's use in TED patients regardless of disease activity or duration.

PRACTICE GUIDELINES AND POSITION STATEMENTS
European Thyroid Association/European Group on Graves' Orbitopathy
The Guidelines for the Management of Graves' Orbitopathy addressing the treatment of TED was updated in 2021. The guidelines recommended high-dose systemic glucocorticoids for first-line treatment for moderate-to-severe and active TED with multiple second-line recommended therapies. Teprotumumab is noted to be a very promising drug recommended as a second line option (EUGOGO, 2021).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Tepezza (teprotumumab-trbw) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Tepezza (teprotumumab-trbw) include: no labeled contraindications.

Exclusions/Discontinuation:
Based on its mechanism of action inhibiting IGF-1R, Tepezza may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception prior to initiation, during treatment with Tepezza and for 6 months after the last dose of Tepezza.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J3241	Injection, teprotumumab-trbw, 10 mg

AVAILABLE DOSAGE FORMS:
Tepezza SOLR 500MG single-dose vial

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Contraindications/Exclusions/Discontinuation References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update	Q4 2024
REVISION- Notable revisions: Required Medical Information Background References	Q4 2023
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses Background References	Q3 2023
REVISION- Notable revisions: Required Medical Information Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file