09-J3000-64

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Subject: Teprotumumab (Tepezza®) Infusion

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Teprotumumab (Tepezza) is an intravenously (IV) administered insulin-like growth factor 1 receptor (IGF-1R) inhibitor that was approved by the US Food and Drug Administration (FDA) in January 2020 for the treatment of Thyroid Eye Disease (TED). Prior to approval, teprotumumab was granted orphan drug designation by the FDA for the treatment of active thyroid eye disease in May 2013. In April 2023, the indication was modified to "the treatment of Thyroid Eye Disease (TED) regardless of Thyroid Eye Disease activity or duration." The pathogenesis of TED results from autoantibodies [i.e., Graves' disease immunoglobulins (GD-IgG) and thyroid-stimulating immunoglobulins (TSI)] that stimulate orbital fibroblasts causing an upregulation of the IGF-1R/thyroid-stimulating hormone receptor (TSH-R) signaling complex. Activation of this complex leads to production of glycosaminoglycans (e.g., hyaluronan) and an increase in proinflammatory cytokines. This results in progressive inflammation and expansion of retrobulbar fat and muscle tissue. Teprotumumab blocks the stimulatory effects of the autoantibodies on IGF-1R. This reduces inflammation and excessive expansion of fat and muscle in the orbital tissue, thus decreasing the symptoms associated with TED (e.g., proptosis and diplopia).

Thyroid eye disease [a.k.a., Graves' ophthalmopathy (GO), thyroid-associated orbitopathy (TAO), thyroid ophthalmopathy, Graves' orbitopathy, Graves' eye disease, Graves' disease eyes] is disease that causes inflammation and tissue expansion behind the eye leading to proptosis (bulging eyes), which is often accompanied by pain, diplopia, reduced quality of life, and may lead to facial disfigurement. In severe cases, TED can lead to blindness. It is estimated that 40 to 50% of patients with Graves' hyperthyroidism develop TED. Women are 5 times more likely than men to develop TED. Most cases are classified as mild and are characterized by mild to moderate eyelid swelling, proptosis <3 mm above upper limit of normal for race, no or intermittent diplopia, and corneal exposure responsive to lubricants. Patient with TED move from an active progressive period characterized by inflammation to an inactive (fibrotic) phase within 1 to 3 years. Once inactive, most medical interventions have not been shown to be effective. To minimize the damage caused in the active phase of disease, early initiation of therapy is essential. Management of patients with TED includes reversal of hyperthyroidism (and hypothyroidism if caused by treatment of hyperthyroidism), smoking cessation, local measures to reduce ocular surface irritation, and treatment of inflammation in the periorbital tissues. Mild symptoms can often be managed by local measures such as using saline eye drops, wearing sunglasses, and raising the head of the bed at night. Glucocorticoids are a mainstay among medical therapies for treatment of moderate to severe TED symptoms. In patients with severe disease, surgical procedures including strabismus correction, eyelid repair, and orbital decompression (in sight threatening cases) are often required. Teprotumumab is the first drug to be approved by the FDA specifically for the treatment of TED. The teprotumumab clinical

trials leading to initial FDA approval were conducted specifically in patients with active TED. The approval to include treatment of TED regardless of activity or duration was based on the results of a small (n=62), Phase 4 randomized, placebo-controlled trial that demonstrated benefit in the reduction of proptosis in patients with chronic (inactive) TED. Full publication of the results occurred in October 2023. Compared to placebo there was a 1.48 mm reduction (-2.41 mm vs. -0.92 mm) in proptosis, but no improvement in the subset of patients with diplopia. Hearing impairment, an emerging adverse effect of significance for teprotumumab, occurred in 22% of patients vs. 10% for placebo. Additional larger studies are warranted. The current guideline-recommended standard of care for the treatment of proptosis in patients with inactive TED is orbital decompression surgery.

In 2022, a Consensus Statement by the American Thyroid Association and the European Thyroid Association on the Management of Thyroid Eye Disease was published. The document states that intravenous glucocorticoid (IVGC) therapy is a preferred treatment for active moderate-to-severe TED when disease activity is the prominent feature in the absence of either significant proptosis or diplopia. Standard dosing with IVGC consists of IV methylprednisolone at cumulative doses of 4.5 g over approximately 3 months (e.g., 0.5 g weekly x 6 weeks followed by 0.25 g weekly for an additional 6 weeks). Poor response at 6 weeks should prompt consideration for treatment withdrawal and evaluation of other therapies. Rituximab and tocilizumab may be considered for TED inactivation in glucocorticoid-resistant patients with active moderate-to-severe TED. Teprotumumab has not been evaluated in this setting. Teprotumumab is a preferred therapy, if available, in patients with active moderate-to-severe TED with significant proptosis and/or diplopia.

The safety and efficacy of teprotumumab leading to FDA approval was evaluated in two randomized, double-masked, placebo-controlled studies in 171 patients with TED [Study 1 (the phase 3 OPTIC trial, NCT01868997) and Study 2 (a phase 2 trial, NCT03298867)]. Patients were randomized to receive teprotumumab or placebo in a 1:1 ratio. Patients were given IV infusions (10 mg/kg for first infusion and 20 mg/kg for the remaining 7 infusions) every 3 weeks for a total of 8 infusions. Patients had a clinical diagnosis of Graves' disease associated with active TED with a Clinical Activity Score (CAS) of 4 or greater in the more severely affected eye, were euthyroid or had thyroxine and free triiodothyronine levels less than 50% above or below normal limits and had an onset of active TED symptoms within 9 months prior to baseline visit. Prior surgical treatment for TED was not permitted. Proptosis ranged from 16 to 33 mm and 125 patients (73%) had diplopia at baseline. The median age was 52 years (range 20 to 79 years), 86% were White, the majority (73%) were female, and 27% of patients were smokers. The primary endpoint was proptosis responder rate at week 24, defined as the percentage of patients with ≥2 mm reduction in proptosis in the study eye from baseline, without deterioration in the non-study eye (≥2 mm increase) in proptosis. Additional evaluations included signs and symptoms of TED including pain, gaze evoked orbital pain, swelling, eyelid erythema, redness, chemosis, inflammation, clinical activity score and assessments of functional vision and patient appearance. Results for proptosis are found in Table 2.

Table 2

	Study 1			**Study 2**		
	Teprotumumab (n=42)	Placebo (n=45)	Difference (95% CI)	Teprotumumab (n=41)	Placebo (n=42)	Difference (95% CI)
Proptosis responder rate at week 24, % (n)	71% (30)	20% (9)	51% (33, 69)	83% (34)	10% (4)	73% (59, 88)
Proptosis (mm) average change from baseline through week 24, LS Mean (SE)	-2.5 (0.2)	-0.2 (0.2)	-2.3 (-2.8, -1.8)	-2.8 (0.2)	-0.5 (0.2)	-2.3 (-2.8, -1.8)

In Study 2, improvement of proptosis as measured by mean change from baseline was observed as early as 6 weeks and continued to improve through week 24. Similar results were seen in Study 1. Teprotumumab also led to improvement in the less severely impacted "fellow" eye. Diplopia (double vision) was evaluated in a subgroup of patients that had diplopia at baseline in Study 1 and 2. Responder rate at week 24 was 53% (n=35) in the 66 teprotumumab-treated patients vs. 25% (n=25) in the 59 placebo-treated patients. Following discontinuation of treatment in Study 1, 53% of patients (16 of 30 patients) who were proptosis responders at week 24 maintained proptosis response 51 weeks after the

last infusion. A total of 67% of patients (12 of 18) who were diplopia responders at week 24 maintained diplopia response 51 weeks after the last infusion.

POSITION STATEMENT:

Site of Care: If teprotumumab (Tepezza) is administered in a hospital-affiliated outpatient setting, additional requirements may apply depending on the member's benefit. Refer to 09-J3000-46: Site of Care Guideline for Select Specialty Medications.

The use of teprotumumab (Tepezza) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "7"):

1. Member has non-sight threatening, moderate-to-severe thyroid eye disease (TED) [a.k.a., Graves' ophthalmopathy (GO), thyroid-associated orbitopathy (TAO), thyroid ophthalmopathy, Graves' orbitopathy, Graves' eye disease, Graves' disease eyes] confirmed by at least **ONE** of the following:
    a. Lid retraction ≥2 mm
    b. Moderate or severe soft tissue involvement
    c. Exophthalmos ≥3 mm above normal for race and gender
    d. Inconstant or constant diplopia
2. Member has active TED as confirmed by a baseline Clinical Activity Score (CAS) of 3 or greater (on the 7-item scale) in the more severely affected eye – *medical record documentation of the CAS report assessed within the past 90 days must be submitted*
3. Member is euthyroid or has mild hypo or hyperthyroidism defined as free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below normal limits – *laboratory documentation of the member's baseline (within the past 90 days) free thyroxine (T4) **AND** free triiodothyronine (T3) levels must be submitted*
4. **ANY** of the following ("a", "b", or "c"):
    a. Member has severe exophthalmos (a.k.a., proptosis) and/or diplopia for which initial treatment with teprotumumab may be preferred – *medical record documentation of the member's severe exophthalmos and/or diplopia must be submitted*
    b. Member had an inadequate response to, had intolerable adverse effects with, or has a contraindication to at least a 6-week treatment course of high-dose IV glucocorticoids (for example, methylprednisolone 0.5 g weekly) – the specific adverse effect(s) or contraindication(s) must be provided
    c. The member was previously approved for teprotumumab treatment by another health plan **AND** documentation of a health plan-paid claim for teprotumumab during the 90 days immediately before the authorization request is submitted
5. Treatment is prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology
6. Dosage of teprotumumab does not exceed 10 mg/kg* for the first infusion, followed by 20 mg/kg* every 3 weeks for 7 additional infusions

    **The dose is recommended to be rounded down to the nearest 500 mg vial size when the resulting reduction is less than 10% of the maximum allowed dose. For example, a 20 mg/kg dose for an 80 kg member (1,600 mg) can be rounded down to three 500 mg vials (1,500 mg) as this is only a 6% dose reduction.*
7. Member has **NOT** previously received treatment with teprotumumab in their lifetime, or, if currently receiving teprotumumab treatment, has not exceeded 8 total doses

Approval duration: 6 months to allow for 8 total infusions (and not to exceed 8 life-time doses)

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Indicated for the treatment of Thyroid Eye Disease (TED) regardless of Thyroid Eye Disease activity or duration.
- The recommended dose is 10 mg/kg for the initial dose followed by 20 mg/kg every three weeks for 7 additional infusions. Teprotumumab must be reconstituted and diluted prior to infusion. Refer to the product labeling for additional instructions.
- Administer the diluted solution intravenously over 90 minutes for the first two infusions. If well tolerated, the minimum time for subsequent infusions can be reduced to 60 minutes. If not well tolerated, the minimum time for subsequent infusions should remain at 90 minutes, and pre-medication is recommended for subsequent infusions.

Dose Adjustments

- Renal impairment – No clinically significant differences in the pharmacokinetics of teprotumumab were observed in patient with mild to moderate renal impairment (creatinine clearance 30 to 89 mL/min estimated by Cockcroft-Gault Equation). Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no dosage adjustments are needed.
- Hepatic impairment – The effect of hepatic impairment on the pharmacokinetics of teprotumumab is unknown. Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed.

Drug Availability

- 500 mg single-dose vial as a lyophilized powder
- Refrigerate at 2°C to 8°C (36°F to 46°F) in original carton until time of use to protect from light. Do not freeze.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warnings

- **Infusion Reactions** – Teprotumumab may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with teprotumumab. Signs and symptoms of infusion-related reactions include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache and muscular pain. Infusion reactions may occur during any of the infusions or within 1.5 hours after an infusion. Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids and antihistamines. In patients who experience an infusion reaction, consideration should be given to pre-medicating with an

antihistamine, antipyretic, corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

- **Inflammatory Bowel Disease** – Teprotumumab may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD. If IBD exacerbation is suspected, discontinuation use of teprotumumab.
- **Hyperglycemia** – Increased blood glucose may occur in patients treated with teprotumumab. In clinical trials, 10% of patients (two thirds of whom had pre-existing diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with teprotumumab. Ensure patients with hyperglycemia or pre-existing diabetes are under appropriate glycemic control before receiving teprotumumab.
- **Hearing Impairment Including Hearing Loss** – Teprotumumab may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment and consider the benefit-risk of treatment with patients.
- **Pregnancy** – Based on findings in animals and its mechanism of action inhibiting insulin-like growth factor 1 receptor (IGF-1R), teprotumumab may cause fetal harm when administered to a pregnant woman. Therefore, teprotumumab should not be used in pregnancy, and appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months following the last dose. If the patient becomes pregnant during treatment, teprotumumab should be discontinued and the patient advised of the potential risk to the fetus.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J3241	Injection, teprotumumab-trbw, 10 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

H05.831	Thyroid orbitopathy, right orbit
H05.832	Thyroid orbitopathy, left orbit
H05.833	Thyroid orbitopathy, bilateral orbit
H05.839	Thyroid orbitopathy, unspecified orbit

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Clinical Activity Score (CAS): a 7-point scale using classic signs and symptoms of inflammation to detect active TED during physical exams. Each positive criterion on the CAS is given one point. The 7 items are:

- Spontaneous orbital pain
- Gaze-evoked orbital pain
- Eyelid swelling that is considered to be due to Active TED
- Eyelid erythema
- Conjunctival redness that is considered to be due to Active TED
- Chemosis
- Inflammation of the caruncle or plica

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 03/11/26.

GUIDELINE UPDATE INFORMATION:

04/15/20	New Medical Coverage Guideline.
05/08/20	Revision to guidelines consisting of updating the position statement to refer to the inclusion of Tepezza in the Site of Care Guideline for Select Specialty Medications.
07/01/20	Revision: Added HCPCS code C9061.
08/15/20	Revision to guidelines consisting of the position statement
10/01/20	Revision: Added HCPCS code J3241 and deleted codes C9061 and J3590.
04/15/21	Review and revision to guideline consisting of updating the position statement and references.
04/15/22	Review and revision to guideline consisting of updating the description section and references.
05/15/22	Review and revision to guideline consisting of updating the position statement and references.
04/15/23	Review and revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, and references. Updates made based on the 2022 TED Management Consensus Statement from the ATA and the ETA. Added diplopia as a reason for which initial treatment with teprotumumab may be preferred. Medical record documentation must be submitted. The corticosteroid step now only includes IV treatment. CAS documentation must be within 90 days of the request.
06/15/23	Revision to guideline consisting of updating the description, position statement, dosage/administration section, and references. Treatment of inactive TED (CAS ≤2) is not considered medically necessary.
04/15/24	Review and revision to guideline consisting of updating the description section, position statement, precautions, and references.
04/15/25	Review and revision to guideline consisting of updating the references.

10/01/25	Revision: Added new ICD-10 codes H05.831, H05.832, H05.833, and H05.839, and removed code E05.00.
04/15/26	Review and revision to guideline consisting of updating the dosage/administration section, precautions and references.