

<p>SUBJECT: CLINICAL POLICIES – INJECTABLE MEDICATIONS – TEPEZZA™ (TEPROTUMUMAB-TRBW) FOR THYROID EYE DISEASE</p> <p>POLICY NUMBER: HS-CP-MA I3o</p> <p>EFFECTIVE DATE: DECEMBER 17, 2025</p> <p>SERVICE/PRODUCT LINE: MEDICARE – MEDICAL</p>	<p>Product Line (check all that apply):</p> <p><input type="checkbox"/> All</p> <p><input type="checkbox"/> Group HMO</p> <p><input type="checkbox"/> Individual HMO</p> <p><input type="checkbox"/> PPO</p> <p><input type="checkbox"/> POS</p> <p><input checked="" type="checkbox"/> Medicare</p> <p><input type="checkbox"/> N/A</p>
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These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

When coverage criteria are not fully established by Medicare including but not limited to National Coverage Decisions (NCD), Local Coverage Decisions (LCD), Medicare Manuals and National Coverage Articles, Sharp Health Plan develops Clinical Policies that serve as recommendations for medical necessity decisions. Sharp Health Plan utilizes evidence-based guidelines from nationally recognized professional organizations, peer reviewed medical and scientific literature and evidence-based consensus statements, which are all based on generally accepted standards of care.

I. BENEFIT STATEMENT: Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member’s evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member’s contract benefits in effect at the time of service.

- A. All reviewers must first identify member eligibility and all decisions of this clinical policy are subject to current state and/or federal law. This Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member’s benefit plan, EOC, always supersedes the information in the Clinical Policies.

II. REGULATORY: N/A

III. DESCRIPTION

- A. This policy defines the Sharp Health Plan (Plan) criteria for coverage of medications with a parenteral (IM, SubQ, IV, Intrathecal) route of administration. These are also referred to as a “medical benefit” medication. A separate policy governs medications administered through the pharmacy benefit (Sharp Health Plan Pharmacy Procedure for Formulary and Pharmaceutical Management Procedures Development).
- B. This policy provides information about the use of Tepezza (teprotumumab-trbw) intravenous (IV) injection, an insulin-like growth factor 1 receptor (IGF-1R) inhibitor, indicated for the treatment of Thyroid Eye Disease (TED).

IV. DEFINITIONS

- A. A Qualified Individual is a Sharp Health Plan (Plan) member.
- B. Experimental and Investigational drugs and devices:
 - 1. Considered experimental if the FDA has not issued a specific indication or NDC number for the specific drug or device AND they are currently under investigation in a registered Clinical Trial.
 - 2. The Off-Label Use of an FDA approved prescription drug or device is not considered an experimental/investigational service if this off-label use is not currently being investigated in a registered Clinical Trial.
- C. Biosimilars: A biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already approved by the FDA (known as the original biologic or reference product). Biosimilars are made with the same types of natural sources as the original medication they were compared to; they are given the same way, have the same strength and dosage, and have the same potential side effects. A biosimilar provides the same treatment benefits as the original biologic.
- D. Injection: The introduction of a medicinal substance into the body; either subcutaneous, intramuscular, intravenous, intra-arterial or into other canals or cavities of the body. For purposes of this medical policy, a medication is provided either by a member (self-injectable) or by a medical provider. It is a “shot” or a dosage of medication given by way of a syringe and needle rather than over a period of time, though not to be given as part of a procedure.
- E. Infusion: The slow diagnostic, prophylactic, or therapeutic introduction of fluid or medicinal substance into a vein or tissue given over a period of time.

V. MEDICAL NECESSITY

- A. To be eligible for coverage under this policy, the member must be a Qualified Individual with active Plan membership. Additionally, the provision of physician samples does not guarantee coverage.
- B. Initial criteria:
 - 1. Thyroid Eye Disease (TED) (must meet ALL):
 - a) Diagnosis of Graves’ disease with associated TED (i.e., Graves’ orbitopathy, Graves’ ophthalmopathy).
 - b) Age \geq 18 years.
 - c) Prescribed by specialists in ophthalmology and endocrinology, with expertise in the treatment of Graves’ disease associated with TED.
 - d) Presence of moderately to severely active TED, associated with at least **one** of the following:
 - (1) Lid retraction \geq 2 mm, **OR**
 - (2) Moderate or severe soft tissue involvement, **OR**
 - (3) Exophthalmos \geq 3 mm above normal for race and gender, **OR**
 - (4) Intermittent or constant diplopia. **AND**
 - e) Thyroid function controlled or near control without significant iatrogenic hypothyroidism.

- f) Member has failed an adequate trial of prior treatment with a corticosteroid (at maximally indicated intravenous (or oral) dose) , unless clinically significant adverse effects are experienced, or all corticosteroids are contraindicated.
- g) Member does not require emergent decompressive surgical ophthalmological intervention.
- h) Member is in the active phase of thyroid eye disease defined as a Clinical Activity Score (CAS) of greater than or equal to four (4):

Thyroid Eye Disease Clinical Activity Score	
Component	Scoring if present
Spontaneous retrobulbar pain	1
Pain on attempted upward or downward gaze	1
Redness of eyelids	1
Swelling of eyelids	1
Swelling of caruncle or plica	1
Swelling of conjunctiva (chemosis)	1
Redness of conjunctiva	1

- j) Tepezza must be used as a single agent therapy.
- k) Dose does not exceed a single 10 mg/kg dose for first infusion followed by seven 20 mg/kg infusions given every 3 weeks. (Authorization will be issued for no more than 8 total infusions).

C. Renewal criteria:

1. 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 is unproven and not medically necessary.

VI. NOT MEDICALLY NECESSARY

- A. Any indication that does not meet the above Medical Necessary criteria OR
- B. Evidence of optic neuropathy including but not limited to decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect OR
- C. Member has unresponsive corneal decompensation OR
- D. Member has had prior orbital radiation or surgery for Thyroid Eye Disease OR
- E. More than one course of Tepezza.

VII. PROCEDURE/ATTACHMENTS

- A. All requests for medical injectable coverage will be reviewed by the delegated Plan Medical Group (PMG) or by the Plan, according to its regular and appropriate utilization management process, administered consistent with the Plan benefit.
- B. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this guideline. This Policy provides assistance in determining coverage under the member’s benefit plan.

- C. The terms of a member’s benefit plan summary defined in the evidence of coverage document may differ from the standard benefit plans upon which this guideline is based. In the event of a conflict, the member's specific benefit document supersedes these guidelines.
- D. The medical injectable will be subject to step therapy per SHP Clinical Policy I3- Injectable Medications.

VIII. CODES: N/A

IX. REFERENCES:

- A. Tepezza [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA, Inc.; March 2025.
- B. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. *N Engl J Med.* 2020 Jan 23;382(4):341-352.
- C. Hodgson NM and Rajaii F. Current Understanding of the Progression and Management of Thyroid Associated Orbitopathy: A Systematic Review. *Ophthalmol Ther.* 2019 Dec 10.
- D. Bartalena, L, et al., 2021. The 2021 European Group on Graves' Orbitopathy (EUGOGO) Clinical Practice Guidelines for the Medical Management of Graves' Orbitopathy. *European Journal of Endocrinology*, 185(4), pp. G43-G67.
- E. Grave’s Eye Disease. American Thyroid Association. Accessed September 28, 2021. <https://www.thyroid.org/graves-eye-disease/>
- F. Biologics for Thyroid Eye Disease. American Academy of Ophthalmology. Last updated July 7, 2024. [Biologics for Thyroid Eye Disease - EyeWiki \(aao.org\)](https://www.aao.org/eye-wiki/biologics-for-thyroid-eye-disease)
- G. Burch HB, Perros P, Bednarczuk T, et al. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association. *Thyroid.* 2022;32(12):1439-1470. doi:<https://doi.org/10.1089/thy.2022.0251>

X. REVISION HISTORY:

Date	Modification (Original, Reviewed or Revised)
12/17/25	Original

Approved by: (Signature of VP /CMO)	Approval date: 12/17/25
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