

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Tepezza (teprotumumab-trbw)
BILLING CODE	J3590 (1 unit = 500mg single-dose vial)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital/Infusion Site
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see “Dosage allowed” below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Tepezza (teprotumumab-trbw) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

THYROID EYE DISEASE

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a confirmed diagnosis of Graves’ disease; AND
4. Member has active moderate to severe thyroid eye disease (TED) with a Clinical Activity Score (CAS) of 4 or greater documented in chart notes;
5. Chart notes must be submitted showing that the member is euthyroid or mildly hypo- or hyper-thyroid (defined as having free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the reference normal limits) prior to starting therapy; AND
6. Member has tried and failed a 12-week course of a high-dose systemic corticosteroid (e.g. methylprednisolone) or has a significant intolerance or contraindication to corticosteroids.
7. **Dosage allowed:** 10mg/kg initial dose intravenously followed by seven 20mg/kg infusions every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 24 weeks.

For **reauthorization**:

Retreatment will not be authorized due to a lack of robust literature available to support the use of Tepezza beyond 24 weeks.

CareSource considers Tepezza (teprotumumab-trbw) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
04/22/2020	New policy for Tepezza created.

References:

1. Tepezza Prescribing Information. Lake Forest, IL: Horizon Therapeutics USA, Inc.; January 2020. Available at: <https://www.hzndocs.com/TEPEZZA-Prescribing-Information.pdf>. Accessed April 22, 2020.
2. NCT03298867 in ClinicalTrials.gov. NIH U.S. National Library of Medicine. Accessed April 22, 2020.

3. NCT03461211 in ClinicalTrials.gov. NIH U.S. National Library of Medicine. Accessed April 22, 2020.
4. Douglas S. Ross, Henry B. Burch, David S. Cooper, M. Carol Greenlee, Peter Laurberg, Ana Luiza Maia, Scott A. Rivkees, Mary Samuels, Julie Ann Sosa, Marius N. Stan, and Martin A. Walter. *Thyroid*. Oct 2016. 1343-1421. <http://doi.org/10.1089/thy.2016.0229>
5. Bartalena L, Baldeschi L, Boboridis K, Eckstein A, Kahaly G, J, Marcocci C, Perros P, Salvi M, Wiersinga W, M: The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. *Eur Thyroid J* 2016;5:9-26. doi: 10.1159/000443828.

Effective date: 05/25/2020

Revised date: 04/22/2020