PROVIDER POLICIES & PROCEDURES

TEPEZZA® (TEPROTUMUMAB-TRBW)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for TEPEZZA® (teprotumumab-trbw). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Tepezza is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of thyroid eye disease. Thyroid eye disease (also commonly referred to as Graves' orbitopathy or ophthalmopathy) is an autoimmune disease of the orbit and retro-ocular tissues typically occurring in individuals with Grave's disease. The disease is characterized by proptosis leading to eye pain, double vision, and difficulty closing the eyelid.

CLINICAL GUIDELINE

Coverage decisions for the use of Tepezza will be made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage decisions are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

A. The individual is 18 years of age or older; **AND**
B. The individual has thyroid eye disease (TED); **AND**
C. Tepezza is prescribed by or in consultation with an ophthalmologist; **AND**
D. The individual has not previously completed a full course of treatment with Tepezza; **AND**
E. The Provider will follow all FDA approved prescribing information for dosing

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of Tepezza is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for Tepezza:

1. Fully completed State of Connecticut, Department of Social Services HUSKY Health Program Tepezza Prior Authorization Request form (to include physician's order and signature); and

2. Clinical information supporting the medical necessity of the treatment as outlined above.

Requesting Authorization
Requests for the prior authorization of Tepezza must be submitted by the ordering physician and faxed to the number listed on the request form. Questions regarding this form should be directed to the HUSKY Health Program Utilization Management Department at 1.800.440.5071 (select option for medical authorizations).

Initial Authorization
If approved, authorization will be given for up to 8 doses.

Reauthorization
Not applicable

EFFECTIVE DATE
This Policy for the prior authorization of Tepezza for individuals covered under the HUSKY Health Program is effective February 1, 2023.

LIMITATIONS
N/A

CODE:

Code	Definition
J3241	Injection, teprotumumab-trbw, 10 mg

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate

an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

- Bartalena L, Kahaly L, Baldeschi L, et al. The 2021 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of Graves' orbitopathy. Eur J Endocrinol. 2021;185(4):G43-G67.
- Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020;382(4):341-352. doi:10.1056/NEJMoa1910434
- Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. Thyroid. 2016;26(10):1343-1421.
- Tepezza [package insert]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; Revised April 2023
- UptoDate: [website] Waltham, MA: Walters Kluwer Health; 2022. Davies T, Burch H. Treatment of Thyroid Eye Disease. Accessed on November 14, 2022.

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	January 2023	Approved at the CHNCT Medical Reviewer meeting on December 14, 2022. Approved by the CHNCT Clinical Quality Subcommittee on December 19, 2022. Approved by DSS on December 22, 2022.
Update	June 2023	Updated Clinical Guideline section. Removed dose recommendations and replaced with statement that specifies provider will follow all FDA approved prescribing and dosing. Removed the following requirements: active TED, CAS >4 and moderate to severe disease. Added statement regarding individuals having previously completed a full course of treatment. Changes approved at the May 10, 2023, Medical Reviewer Meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on June 19, 2023. Approved by DSS on June 28, 2023.