pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 30, 2023	July 10, 2023	*See below

SUBJECT

Prior Authorization of Tepezza (teprotumumab-trbw) – Pharmacy Services

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Tepezza (teprotumumab-trbw) submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Tepezza (teprotumumab-trbw) to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Tepezza (teprotumumab-trbw) based on recent changes to the package labeling

*01-23-20	09-23-20	27-23-14	33-23-20
02-23-13	11-23-13	30-23-17	
03-23-13	14-23-13	31-23-21	
08-23-24	24-23-19	32-23-13	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

to remove the guideline that the beneficiary has documentation of active thyroid eye disease and remove the guideline that the beneficiary is euthyroid or has mild hypo- or hyperthyroidism.

The revisions to the guidelines to determine medical necessity of prescriptions for Tepezza (teprotumumab-trbw) submitted for prior authorization were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Tepezza (teprotumumab-trbw) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Tepezza [teprotumumab-trbw]) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

I. Requirements for Prior Authorization of Tepezza (teprotumumab-trbw)

A. Prescriptions That Require Prior Authorization

All prescriptions for Tepezza (teprotumumab-trbw) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Tepezza (teprotumumab-trbw), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Tepezza (teprotumumab-trbw) for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed Tepezza (teprotumumab-trbw) by or in consultation with an endocrinologist, ophthalmologist, or ocular surgeon specializing in the treatment of thyroid eye disease; **AND**

5. Is prescribed as part of a multidisciplinary treatment approach that includes consultation with both endocrinology and ophthalmology specialties; **AND**

6. Does not have a history of a contraindication to the prescribed medication; **AND**

7. Has documentation of diagnosis of moderate-severe thyroid eye disease, defined as at least **one** of the following:

   a. Lid retraction of ≥2 mm,
   b. Moderate or severe soft-tissue involvement,
   c. Proptosis ≥3 mm above normal values,
   d. Periodic or constant diplopia;

   AND

8. Has a history of therapeutic failure of or a contraindication or an intolerance to a systemic corticosteroid.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the

professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Tepezza (teprotumumab-trbw). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

The Department of Human Services will limit authorization of prescriptions for Tepezza (teprotumumab-trbw) consistent with the FDA-approved package labeling.

E. References

1. Bartalena L, Baldeschi L, Boboridis, et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy guidelines for the management of Graves' orbitopathy. *Eur Thyroid J*. 2016;5(1):9-26.
2. Davis T.F. et al. Treatment of Graves' orbitopathy (ophthalmopathy). Up To Date, accessed September 30, 2020.
3. Douglas R, Patel K, Sile S, et al. Teprotumumab for the treatment of active thyroid eye disease. *N Engl J Med*. 2020;382:341-352.
4. 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):1343-421.
5. Smith T, Kahaly G, Ezra D, et al. Teprotumumab for thyroid-associated ophthalmopathy. *N Engl J Med*. 2017;376(18):1748-1761.
6. Tepezza [prescribing information]. Horizon Therapeutics. April 2023.