DRUG DETERMINATION POLICY

Title: DDP-46 Tepezza for Thyroid Eye Disease

Effective Date: 11/09/2021

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Tepazza is a specialty drug used to treat Thyroid Eye Disease (TED). These criteria were developed and implemented to ensure appropriate use for the intended diagnosis, severity of disease and place in therapy.

3.0 Clinical Determination Guidelines:

A. Thyroid Eye Disease [must meet all listed below]:

   1. Age: at least 18 years.

   2. Prescriber: prescribed by or in consultation with a specialist in the treatment of Graves' disease associated with thyroid eye disease (endocrinologist, ophthalmologist).

   3. Diagnosis and severity [must meet all listed below]:

      a. Active moderate-to severe thyroid eye disease related to Graves' disease (also known as Graves orbitopathy).

      b. Clinical Activity Score: at least 4 in the more severely affected eye (see Appendix 2).

      c. Treated Thyroid disease: euthyroid OR has mild hypo-or hyperthyroidism.

      d. Surgical ophthalmological intervention NOT required.

4. Other therapies: contraindication, inadequate response to one or both below depending on response or significant side effects.

    a. Moderate disease: prednisone 30mg per day orally for four weeks.

    b. Severe disease: methylprednisolone intravenous 500mg weekly for six weeks, then 250mg weekly for six weeks.

5. Dosage regimen:

    a. Tepezza intravenous (teprotumumab IV): 10mg per Kg initial dose, then three weeks later 20mg per Kg every three weeks for seven doses.

    b. Not in combination with other biological immunomodulators (e.g. Rituxan and biosimilars, Actemra, Kevzara).

6. Approval:

    a. Initial: seven months.

    b. Reapproval: not indicated, limited to one eight infusion course per lifetime.

B. Appropriate medication use [must meet one listed below]:

1. Food and Drug Administration (FDA) approval status [must meet one listed below]:

    a. FDA approved: product, indication, and/or dosage regimen.

    b. Non-FDA approved: compendium support (Lexi comp™) for use of a drug for a non- FDA approved indication or dosage regimen.

2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

4.0 Coding:

AFFECTED CODES				
Code	**Brand Name**	**Generic Name**	**Billing Units (1U)**	**Prior Approval**
J3241	Tepazza	Teprotumumab-trbw	10mg	Y

5.0 References, Citations & Resources:

1. Lexi comp, Lexi comp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Tepezza, accessed September 2021.
2. UpToDate Treatment of Grave's orbitopathy (ophthalmopathy) accessed June 2020.
3. Randomized, single blind trial of intravenous versus oral steroid monotherapy in Graves Orbitopathy J. Clin. Endocrininol. Metab. 2005;90:5234.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 11/09/2021

Next Review Date: 07/2021

Revision Date	Reason for Revision
8/21	Annual review; clarified criteria instructions, added appropriate use section; updated HCPCS code for drug

Appendix 1 Monitoring and Patient Safety

Drug	Adverse Reactions	Monitoring and Contraindications	REMS
Tepezza teprotumumab	• Dermatological: alopecia (13%) • Gastrointestinal: nausea (17%), diarrhea (12%) • Central Nervous System: fatigue (12%) • Neuromuscular and Skeletal: muscle spasm (25%)	• Gastrointestinal: inflammatory bowel disease flare • Infusion reaction • Labs: blood glucose	None needed

Appendix 2: Thyroid Eye Disease Clinical Activity Score (CAS)

Clinical Activity Score

- Add 1 point for each finding
- Symptoms
  - Pain or pressure in a periorbital or retroorbital distribution
  - Pain with upward, downward, or lateral eye movement
- Signs
  - Swelling of the eyelids
  - Redness of the eyelids
  - Conjunctival injection
  - Chemosis
  - Inflammation of the caruncle or plica
- Changes
  - Increase in measured proptosis $\geq$ 2 mm over 1-3 months
  - Decrease in eye movement limit of $\geq$ 8º over 1-3 months
  - Decrease in visual acuity (2 Snellen chart lines) over 1-3 months

Mourits MP, Koornneef L, Wiersinga WM, Prummel MF, Berghout A, van der Gaag R. Br J Ophthalmol. 1989 Aug;73(8):639-44.