Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 217.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Tepezza (teprotumumab-trbw)

I. Policy:
Tepezza (teprotumumab-trbw)

II. Purpose/Objective:
To provide a policy of coverage regarding Tepezza (teprotumumab-trbw)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Tepezza (teprotumumab-trbw) is an Insulin-Like Growth Factor-1 Receptor (IGF-1R) Antagonist, Monoclonal Antibody that binds to insulin-like growth factor-1 receptor inhibitor and blocks its activation and signaling. Teprotumumab's mechanism of action in patients with thyroid eye disease has not been fully characterized.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Tepezza (teprotumumab-trbw) will be considered medically necessary for the Medicaid line of business when ALL of the following criteria are met:

- Prescription written by an ophthalmologist **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Grave's disease **AND**
- Medical record documentation of moderate to severe Thyroid Eye Disease with documentation of one or more of the following: lid retraction of ≥ 2mm, moderate or severe soft-tissue involvement, proptosis ≥ 3 mm above normal values for race and sex; and periodic or constant diplopia **AND**
- Medical record documentation that the member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels <50% above or below normal limits) prior to starting Tepezza therapy OR patient has been initiated on anti-thyroid medication **AND**
- Medical record documentation that the member is being prescribed an appropriate dose and duration of Tepezza (10 mg/kg as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to systemic steroids.

AUTHORIZATION DURATION: Approval will be for one **(1) 6 month authorization** for the FDA-approved **maximum of 8 doses of Tepezza.** Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

Tepezza (teprotumumab-trbw) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescription written by an ophthalmologist **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Grave's disease **AND**
- Medical record documentation of moderate to severe Thyroid Eye Disease with documentation of one or more of the following: lid retraction of ≥ 2mm, moderate or severe soft-tissue involvement, proptosis ≥ 3 mm above normal values for race and sex; and periodic or constant diplopia **AND**
- Medical record documentation that the member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels <50% above or below normal limits) prior to starting Tepezza therapy **AND**
- Medical record documentation that the member is being prescribed an appropriate dose and duration of Tepezza (10 mg/kg as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses)

AUTHORIZATION DURATION: Approval will be for one **(1) 6 month authorization** for the FDA-approved **maximum of 8 doses of Tepezza.** Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Tepezza (teprotumumab-trbw) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Prescription written by an ophthalmologist **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Grave's disease **AND**
- Medical record documentation of moderate to severe Thyroid Eye Disease with documentation of one or more of the following: lid retraction of ≥ 2mm, moderate or severe soft-tissue involvement, proptosis ≥ 3 mm above normal values for race and sex; and periodic or constant diplopia **AND**
- Medical record documentation that the member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels <50% above or below normal limits) prior to starting Tepezza therapy **AND**
- Medical record documentation that the member is being prescribed an appropriate dose and duration of Tepezza (10 mg/kg as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to systemic steroids.

AUTHORIZATION DURATION: Approval will be for one **(1) 6 month authorization** for the FDA-approved **maximum of 8 doses of Tepezza.** Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.
Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/21/20

Revised: 5/9/23 (LOB carve out, Medicaid business segment)**,** 6/30/23 (anti-thyroid medication per DHS)

Reviewed: 6/8/21, 5/11/22 (Medicaid PARP statement)