Clinical Policy: Teprotumumab (Tepezza)

Reference Number: LA.PHAR.465
Effective Date:
Last Review Date: 03.21
Line of Business: Medicaid

Coding Implications Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Teprotumumab (Tepezza™) is an insulin-like growth factor 1 receptor (IGF-1R) inhibitor.

FDA Approved Indication(s)

Tepezza is indicated for the treatment of thyroid eye disease (TED).

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Tepezza is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Thyroid Eye Disease (must meet all):

1. **Diagnosis of Graves' disease with associated TED (i.e., Graves' ophthalmopathy, Graves' orbitopathy);**
2. **Member has active TED with a clinical activity score (CAS) of ≥ 4 (see *Appendix D*);**
3. **Prescribed by or in consultation with an ophthalmologist;**
4. **Age ≥ 18 years;**
5. **Member is euthyroid with documentation of a recent (within the last 30 days) free thyroxine (FT4) and free triiodothyronine (FT3) levels within the laboratory defined reference range;**
6. **Member has not had previous surgical intervention for TED;**
7. **Member does not require surgical ophthalmological intervention;**
8. **Failure of a 4-week trial of a systemic corticosteroid (at up to maximally indicated doses), unless clinically significant adverse effects are experienced or all are contraindicated;**
9. **Member has not received ≥ 8 Tepezza infusions (including the initial 10 mg/kg first infusion);**
10. **Dose does not exceed a single 10 mg/kg dose followed by seven 20 mg/kg infusions given every 3 weeks.**

Approval duration: 6 months (up to 8 total lifetime infusions)

B. Other diagnoses/indications
1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. Thyroid Eye Disease (must meet all):
1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy as evidenced by both of the following (a and b):**
   a. **Reduction in proptosis ≥ 2 mm;**
   b. **Reduction in CAS from baseline of ≥ 2 points;**
3. **Member has not had previous surgical intervention for TED;**
4. **Member does not require surgical ophthalmological intervention;**
5. **Member has not received ≥ 8 Tepezza infusions (including the initial 10 mg/kg first infusion);**
6. **If request is for a dose increase, new dose does not exceed a total of seven 20 mg/kg infusions given every 3 weeks.**

Approval duration: 6 months (up to 8 total lifetime infusions)

B. Other diagnoses/indications
1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CAS: clinical activity score
FDA: Food and Drug Administration
TED: thyroid eye disease

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
prednisone	30 mg/day PO	30 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methylprednisolone (SOLU-Medrol®)	500 mg IV once weekly for weeks 1 to 6, then 250 mg IV once weekly for weeks 7-12	500 mg/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- The Graves' orbitopathy CAS elements below are each assigned a score of 1. Graves' orbitopathy is considered active in patients with a CAS of ≥ 3 (Ross et al., 2016 American Thyroid Association Guidelines). The Phase 3 clinical trial evaluating teprotumumab enrolled patients with a CAS of ≥ 4 (Smith et al. 2017).
  - Painful feeling behind the globe over last four weeks
  - Pain with eye movement during last four weeks
  - Redness of the eyelids
  - Redness of the conjunctiva
  - Swelling of the eyelids
  - Chemosis (edema of the conjunctiva)
  - Swollen caruncle (flesh body at medial angle of eye)
  - Increase in proptosis ≥ 2 mm
  - Decreased eye movements ≥ 5° any direction
  - Decreased visual acuity ≥ 1 line on Snellen chart

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
TED	Initial: 10 mg/kg IV one time dose Maintenance: 20 mg/kg IV every 3 weeks for seven infusions	See dosing regimen

VI. Product Availability
Single-dose vial: 500 mg

VII. 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 November 4, 2020.
2. NCT03298867 in ClinicalTrials.gov. NIH U.S. National Library of Medicine. Accessed January 15, 2020.
3. 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; 26:1343.

4. **Mourits MP, Prummel MF, Wiersinga WM, Koornneef L. Clinical activity score as a guide in the management of patients with Graves' ophthalmopathy. Clin Endocrinol (Oxf) 1997; 47:9.**
5. **Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopoathy. NEJM 2017; 376 (18): 1748-1761.**

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9061	Injection, teprotumumab-trbw, 10 mg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	03.2021

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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