Tepezza

I. Generic Name:
- a. Teprotumumab

II. Brand Name:
- a. Tepezza

III. Medication Class:
- a. Monoclonal antibody; Insulin-like growth factor-1 receptor (IGF-1R) antagonist

IV. FDA Approved Uses:
- a. Thyroid eye disease: Treatment of thyroid eye disease

V. Application of Criteria:
- a. The following criteria apply to Michigan Medicaid, Illinois Medicaid, and Meridian Choice (HIX)

VI. Criteria for Use:
- a. Documentation of an FDA approved indication
- b. Member must be 18 years of age or older
- c. Request submitted by Endocrinology with Ophthalmology consult
- d. Current clinical documents with plan of care recommending treatment with Tepezza
- e. Documentation of reversal of hyperthyroidism if present
- f. Documentation of use of local measures (e.g. eye shades, artificial tears, raising head of the bed at night)
- g. Documentation that the member is currently not smoking and has not smoked in the previous 6 months
- h. Clinical evidence of moderate to severe or progressive symptoms
- i. Documentation that symptoms began within 9 months of starting therapy
- j. Clinical documentation of adequate trial and failure of oral and IV glucocorticoids
- k. Clinical documentation of adequate trial and failure of mycophenolate mofetil

VII. Required Medical Information:
- a. Proper diagnosis and documentation of an FDA approved indication
- b. Current endocrinology and ophthalmology progress notes detailing the diagnosis with current plan of care
- c. Complete endocrinology and ophthalmology progress notes documenting the disease and treatment history

d. Documentation of dose, date ranges of therapy, and clinical outcomes for all medications previously tried and failed
e. Current negative serum cotinine lab work and progress notes documenting that the member has not smoked in the previous 6 months
f. Chart notes showing compliance to previous therapy and office visits

VIII. Contraindications:

a. There are no contraindications listed in the manufacturer's labeling

IX. Not Approved If:

a. Patient shows non-compliance with previous treatment
b. Patient has severe disease that requires surgery
c. Patient has mild disease
d. Request is for a non-FDA approved indication or dose
e. Member is a current smoker or has smoked in the previous 6 months
f. Request for additional courses of treatment (only one course of treatment is covered when criteria for coverage are met)

X. Length of Authorization:

a. Initial: Two doses
b. Continuation: Three doses
c. Maximum of 8 doses allowed total with documentation of tolerance and plan to continue therapy with each request

XI. Dosing:

a. 10 mg/kg IV as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses

XII. Criteria for Continuation of Therapy:

a. Initial therapy was tolerated
b. Patient must be compliant with taking the medication as prescribed
c. Patient must not be experiencing any severe adverse reaction while taking the medication
d. Current office visit notes/clinical update submitted with each request

XIII. Criteria for Discontinuation of Therapy:

a. Patient is non-compliant with pharmacologic/non-pharmacologic therapy
b. No demonstrable clinically significant improvement after initiation and stabilization of drug therapy

c. Patient is non-responsive to FDA-approved dosing
d. There is evidence that the member is smoking

XIV. References:

1. Facts and Comparisons. Wolters Kluwer Health. April 2020.
2. Tepezza (teprotumumab) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA Inc: January 2020.
3. Bartalena L, Marcocci C, Bogazzi F, et al. Relation between therapy for hyperthyroidism and the course of Graves' ophthalmopathy. N Engl J Med 1998; 338:73.
4. 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.[PubMed 31971679]10.1056/NEJMoa1910434
5. Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for thyroid-associated ophthalmopathy. N Engl J Med. 2017; 376(18):1748-1761.[PubMed 28467880]10.1056/NEJMoa1614949
6. Tanda ML, Piantanida E, Liparulo L, et al. Prevalence and natural history of Graves' orbitopathy in a large series of patients with newly diagnosed graves' hyperthyroidism seen at a single center. J Clin Endocrinol Metab 2013; 98:1443.
7. Piantanida E, Tanda ML, Lai A, et al. Prevalence and natural history of Graves' orbitopathy in the XXI century. J Endocrinol Invest 2013; 36:444.
8. Ye X, Bo X, Hu X, et al. Efficacy and safety of mycophenolate mofetil in patients with active moderate-to-severe Graves' orbitopathy. Clin Endocrinol (Oxf) 2017; 86:247.

Approved by: _____ Date: _____
CMO

Initial Approval:	
Revised:	
Annual Review:	
Next Review Date:	