SmartPA Criteria Proposal

Drug/Drug Class:	Tepezza Clinical Edit
First Implementation Date:	November 19, 2020
Revised Date:	N/A
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Tepezza™ (teprotumumab-trbw)

Why Issue Selected: Tepezza™ (teprotumumab-trbw) was FDA approved on January 21, 2020, in adults for the treatment of thyroid eye disease (TED), also known as Graves' orbitopathy. Tepezza is an insulin-like growth factor-1 (IGF-1) receptor inhibitor; it is believed that immunoglobulins signal insulin-like growth factor in patients with Graves' disease. TED is a rare condition where the muscles and fatty tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards (proptosis). Proptosis is often accompanied by pain and diplopia and in some cases, facial disfigurement. Blindness has been reported in severe cases, and the disease can have negative impacts on quality of life. It is believed there are 15,000-20,000 individuals in the United States with TED. Roughly 90% of TED patients have Graves' disease, and 40% of Graves' disease patients have TED. In clinical trials a Clinical Activity Score was used to measure disease severity. Tepezza is given as an outpatient infusion for 8 total doses; dosing is initiated with 10mg/kg for the first infusion followed by 20mg/kg every 3 weeks for a total of 8 doses over 24 weeks. Re-treatment is not currently supported by clinical data. Tepezza's label includes several warnings, including exacerbation of preexisting inflammatory bowel disease, hyperglycemia, and fetal harm in pregnant women.

Program-Specific Information:

Date Range FFS 4-1-2019 to 3-31-2020				
Drug	**Claims**	**Spend**	**Cost per vial (MAC)**	**Cost per 8 dose therapy for 70kg patient**
TEPEZZA 500MG VIAL	0	-	$14,840.40	$341,329.20

Type of Criteria:
☒ **Increased risk of ADE** ☐ **Preferred Drug List**
☒ **Appropriate Indications** ☒ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Tepezza™ (teprotumumab-trbw)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

- Participant is aged 18 years or older **AND**
- Prescribed by or in consultation with an ophthalmologist, endocrinologist, or other appropriate specialist for the treated disease state **AND**
- Documentation of active moderate to severe TED defined as 2 or more of the following:
    - Lid retraction of >2mm
    - Moderate or severe soft-tissue involvement
    - Proptosis ≥ 3mm above ULN for race and sex
    - Periodic or constant diplopia
    - Documented diagnosis of exophthalmos **AND**
- Documentation of baseline Clinical Activity Score ≥ 4 **AND**
- Failure to achieve desired therapeutic outcomes with an adequate therapeutic trial of glucocorticoids (defined as at least 1 month of therapy) or documented ADE/ADRs or contraindications to glucocorticoid therapy **AND**
- Documentation of labs reporting participant is euthyroid prior to initiation of treatment **AND**
- For participants with a diagnosis of diabetes, adequately controlled blood glucose prior to initiation of treatment **AND**
- Participant is currently not pregnant

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds 8 doses per lifetime

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- Tepezza (teprotumumab) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA Inc; January 2020.
- 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
- 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
- Ross D, Burch H, Cooper D, et al. 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis. 2016; 26(10): 1-79. Accessed at https://liebertpub.com/doi/pdf/10.1089/thy.2016.0229
- IPD Analytics Rx Insights_New Drug Approval Review_Tepezza_02 2020