SmartPA Criteria Proposal

Drug/Drug Class:	Tepezza Clinical Edit
First Implementation Date:	October 1, 2020
Revised Date:	November 2, 2023
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. On April 14 2023, Tepezza received and expanded indication for treatment of all patients with TED of any activity or duration, rather than only those patients with acute disease manifestations. 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. Due to the possible adverse events and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Tepezza.

Program-Specific Information:

Date Range FFS 4-1-2022 to 3-31-2023			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
TEPEZZA 500 MG VIAL	13	$790,726.41	$60,825.11

Type of Criteria:
☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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**
- Documented diagnosis of TED **AND**
- Proptosis ≥ 3mm above ULN for race and sex, or ≥ 3mm above patient's baseline **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

Denial Criteria

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

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; April 2023.
- 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. New Drug Review: Tepezza (teprotumumab-trbw). February 2020.