Pharmacy Policy

Tepezza

Policy Number: 9.705
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Tepezza (teprotumumab-trbw)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	▪ All FDA approved indications not otherwise excluded
Required Medical Information	Documentation of all of the following: 1. Diagnosis of Thyroid Eye Disease (TED) that is associated with Graves' Disease ***AND*** 2. Member has moderately to severely active TED with a Clinical Activity Score (CAS) ≥ 4 (see appendix A) which includes one of the following elements- o Lid retraction ≥ 2 mm o Moderate to severe soft tissue involvement o Exophthalmos ≥ 3 mm above normal

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	o Inconstant or constant diplopia: ***AND*** 3. Onset of TED symptoms occurred within the previous 9 months; ***AND*** 4. Member is euthyroid with documentation of a recent (within the last 30 days) free thyroxine (FT4) and free triiodothyronine (FT3) levels within laboratory defined reference range ;***AND*** 5. Member has not had prior surgical treatment and does not require surgical intervention for TED; ***AND*** 6. If the member has acute inflammatory symptoms, member has had an inadequate response, contraindication or intolerance to a 4 week trial of corticosteroid therapy at maximally indicated doses; ***AND*** 7. Dose does not exceed a single 10 mg/kg dose followed by seven 20 mg/kg infusions given every 3 weeks
Age Restriction	▪ 18 years and older
Prescriber Restriction	▪ Prescribed by or in consultation with Ocuplastic surgeon or Neuro Ophthalmologist
Coverage Duration	▪ 6 months
Quantity Limit	▪ Lifetime limit of 8 infusions including initial infusion
Other criteria	Reauthorization: Documentation of **ALL** of the following: 1. Positive response to therapy as evidenced by both: a. ≥ 2 mm reduction in proptosis from baseline b. Reduction in CAS from baseline of ≥ 2 points 2. Member does not require surgical ophthalmological intervention 3. Member has not received ≥ 7 infusions (not including the initial infusion) 4. Dose does not exceed a total of seven 20mg/kg infusions given every 3 weeks

Appendix A: General information

Clinical Activity Score (CAS): It is a seven point scale to detect signs and symptoms of active TED with a score of 3 or more indicating active disease. Clinical Activity Score Elements include:

- 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)

Clinical Background Information and References

1. Tepezza (teprotumumab-trbw) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA, Inc.; January 2020.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.203 Tepezza Policy retired; new policy created	1/1/2021	P&T Committee

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers

in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.