ALASKA MEDICAID
Prior Authorization Criteria

Tepezza®
(teprotumumab-trbw)

FDA INDICATIONS AND USAGE[1]

Tepezza® is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease.

APPROVAL CRITERIA[1,2,3,4]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a specialist in ophthalmology, endocrinology, oculoplastic surgery or neuro-ophthalmology **AND**;
3. Patient has diagnosis of Graves' disease **AND**;
4. Patient has documentation of one of the following:
   a. Member is euthyroid **OR**;
   b. Member has mild hypo- or hyperthyroidism (free thyroxine [FT4] and free triiodothyronine [FT3] levels <50% above or below the normal limits) **AND**;
5. Patient has documentation of a Clinical Activity Score of at least 4 in the more severely affected eye(s) **AND**;
6. Patient has active phase TED that is non-sight threatening but has a significant impact on daily living (I.E., lid retraction ≥ 2 mm, moderate or severe soft tissue involvement, exophthalmos ≥ 3 mm above normal for race and gender, and/or inconstant or constant diplopia) **AND**;
7. Documentation of an inadequate response, or there is a contraindication or intolerance to high dose glucocorticoid therapy for at least one month **AND**;
8. For female patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient has poorly or uncontrolled diabetes.

CAUTIONS[1]

- If an infusion reaction occurs, interrupt or slow the rate of infusion and use appropriate medical management.
- Monitor patients with preexisting IBD for flare of disease; discontinue Tepezza® if IBD worsens.
- Monitor glucose levels in all patients; treat hyperglycemia with glycemic control medications

DURATION OF APPROVAL

- Initial Approval: 6 months
- Reauthorization not approved. The treatment is 8 infusions total given every 3 weeks.

QUANTITY LIMIT[1]

- Initiate dosing with 10 mg/kg for first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions
- HCPCS – J3490

REFERENCES / FOOTNOTES:

1. Tepezza [package insert]. Dublin, Ireland; Horizon Therapeutics Ireland, DAC, October 2021. Accessed September 2022.
2. Douglas RS, Kahaly GJ, Patel A, Sile S, Thompson EHZ, Perdok R, Fleming JC, Fowler BT, Marcocci C, Marinò M, Antonelli A, Dailey R, Harris GJ, Eckstein A, Schiffman J, Tang R, Nelson C, Salvi M, Wester S, Sherman JW, Vescio T, Holt RJ, Smith TJ. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020 Jan 23;382(4):341-352.
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(10):1343.
4. Terry F. Davies, Henry B.Barch, last update May, 2020. Treatment of Graves' orbithopthy (ophthalmopathy).