Teprotumumab (Tepezza) – PA Criteria

HCPC: J3241

Tepezza is a fully human insulin-like growth factor-1 (IgG1) monoclonal antibody that competitively inhibits the IgG1 receptor. It is indicated for the treatment of Thyroid Eye Disease (TED) and is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Individual is ≥18 years of age
  - Therapy is prescribed by, or in consultation with, an endocrinologist **and** an ophthalmologist with expertise in the treatment of Grave's disease associated with TED
  - Individual has had an inadequate response (trial of ≥60 days), contraindication or intolerance to corticosteroids used for the treatment of TED (Ex. prednisone, methylprednisolone, dexamethasone)
  - Individual has a diagnosis of moderate to severe TED associated with at least **one** of the following:
    - Lid retraction ≥ 2 mm
    - Moderate or severe soft tissue involvement
    - Exophthalmos ≥ 3 mm above normal for race and gender
    - Intermittent or constant diplopia
  - Documentation is provided indicating **one** of the following:
    - Individual is euthyroid with thyroid function in normal range
    - Individual has mild hypothyroidism or hyperthyroidism (defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels < 50% above or below the normal limits) and is undergoing treatment to correct and/or maintain euthyroid
  - Documentation is providing indicating a TED clinical activity score of ≥4

Clinical Activity Score for Graves Orbitopathy	
For each item present, one (1) point is given. The sum of these points is the clinical activity score	
Pain	Painful or oppressive feeling on or behind the globe, during the last 4 weeks
	Pain with eye movement during the last 4 weeks
Redness	Redness of eyelids(s)
	Diffuse redness of the conjunctiva, covering at least 1 quadrant
Swelling	Swelling of the eyelid(s)
	Chemosis
	Swollen caruncle
	Increase of proptosis of ≥ 2mm during a period of 1-3 months
Impaired function	Decrease of eye movements in any direction ≥ 5° during a period of 1-3 months
	Decrease of visual acuity of ≥ 1 line(s) on the Snellen chart (using a pinhole) during a period of 1-3 months

  - Individual does not require immediate surgical ophthalmological intervention
  - Individual does not have clinically significant optic neuropathy (Individual has not had a decrease in best corrected visual acuity (BCVA) within the previous six months, ex., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement
  - Individual does not have corneal decompensation unresponsive to medical management
  - If the individual is a diabetic, they are being managed by an endocrinologist or other provider experienced in the treatment and stabilization of diabetes
  - Individual is not pregnant
  - Approval duration: 6 months (8 infusions per lifetime)
- **Continuation of Therapy: not authorized**