Teplizumab (Tzield) – PA Criteria

HCPC: J9381

Teplizumab (Tzield) is an Anti-CD3 monoclonal antibody indicated for the treatment of Type 1 Diabetes (T1DM) in patients ≥8 years of age to delay progression from stage 2 to stage 3 disease. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Therapy is prescribed or in consultation with an endocrinologist
  - Individual is ≥8 years of age
  - Individual has **at least two** positive pancreatic islet autoantibodies:
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
    - Insulin autoantibody (IAA)
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Islet cell autoantibody (ICA)
  - Individual has stage 2 T1DM disease confirmed by glucose intolerance using an oral glucose tolerance test (OGTT) (or alternative method if appropriate and OGTT is not available) indicating **one** of the following in the previous 2 months:
    - Fasting glucose 110-125 mg/dL
    - 2-hour postprandial plasma glucose 140-199 mg/dL
    - An intervening postprandial glucose level at 30, 60, or 90 minutes of ≥ 200 mg/dL
    - A1C of 5.7%-6.4%
  - Individual has no symptoms of T1DM
  - Individual does not have a suggestion of T2D and has not progressed to stage 3 T1DM
  - Approval duration: one treatment cycle
- **Continuation of Therapy: not authorized**