

**SOUTH DAKOTA MEDICAID
PRIOR AUTHORIZATION CRITERIA**

Physician Administered Drugs, Vaccines, and Immunizations

Teplizumab (Tzielid) – PA Criteria

HCPC: J9381

Teplizumab (Tzielid) 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
 - 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**