



Montana Healthcare Programs Physician-Administered Drug (PAD) Criteria

Tzield® (teplizumab-mzwv)

I. Medication Description

Tzield® is a CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D. Tzield® is the first in class disease-modifying immunotherapy to slow progression from Stage 2 to Stage 3 diabetes.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 8 years of age or older.
- Have confirmed Stage 2 type 1 diabetes documented by BOTH of the following:
 - At least two (2) of the following positive pancreatic islet cell 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)
 - Dysglycemia without overt hyperglycemia using an oral glucose tolerance test. If an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate. Examples are:
 - Fasting plasma glucose level of 100 to 125 mg/dL
 - 2-hour post-prandial glucose of 140 to 199 mg/dL

Prescriber requirements:

- Must be an endocrinologist.
- Must include a current patient body surface area (BSA).
- Prescriber attests to the following:
 - The member has had a complete blood count and liver enzyme tests prior to initiating Tzield®.
 - Prescriber ensures the clinical history of the patient does not suggest type 2 diabetes.

- Prescriber is aware of the risk of cytokine release syndrome, serious infection and other risks associated with TzielD® infusion.

Limitations:

Dosed per package labeling based on body surface area (BSA).

IV. Renewal Coverage Criteria

No renewal is available. This treatment is for a one-time 14-day course.

V. Quantity Limits

Maximum Daily Dose = 14-day dosing regimen based on body surface area

VI. Coverage Duration

Initial approval: 14-day course.

Renewal approval duration: No renewal is available. This treatment is for a one-time 14-day course.

References:

TZIELD Prescribing Information

<https://products.sanofi.us/tzielD/tzielD.pdf>

<https://www.clinicaltrials.gov/study/NCT01030861?term=NCT01030861&rank=1>

[Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2021 | Diabetes Care | American Diabetes Association \(diabetesjournals.org\)](#)