

teplizumab-mzwv (Tzield)

Commercial Medical Benefit Drug Policy

Place of Service

Infusion Center Administration

Office Administration

Outpatient Facility Administration

Drug Details

USP Category: BLOOD GLUCOSE REGULATORS

Mechanism of Action: CD3-directed humanized IgG1 kappa antibody

HCPCS:

J9381:Injection, teplizumab-mzwv, 5 mcg

How Supplied:

2 mg per 2 mL (1 mg/mL) single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Delaying the Onset of Stage 3 or Clinical Type 1 Diabetes Mellitus

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Delaying the Onset of Stage 3 or Clinical Type 1 Diabetes Mellitus

Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with an endocrinologist
2. Patient has family history of type 1 diabetes
3. Patient is at least 8 years of age
4. Documentation is provided the patient has stage 2 type 1 diabetes as confirmed by both of the following criteria:
 - a. Patient has at least two of the following pancreatic islet cell autoantibodies:
 - i. Glutamic acid decarboxylase 65 (GAD65) autoantibodies
 - ii. Insulin autoantibodies (IAA)
 - iii. Tyrosine phosphatase-like protein autoantibodies (IA-2, ICA512)
 - iv. Zinc transporter 8 autoantibody (ZnT8A)

- v. Islet cell autoantibody (ICA)
- b. Patient has dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) or equivalent alternative glycemic test as confirmed by one of the following:
 - i. Fasting plasma glucose between 100 and 125 mg/dL
 - ii. A 2-hour postprandial plasma glucose level between 140 and 199 mg/dL during an OGTT
 - iii. An intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200 mg/dL on two occasions during an OGTT
 - iv. Glycated hemoglobin (A1C) level between 5.7% and 6.4%

Covered Doses:

Given by intravenous infusion at the following schedule:

- Day 1: 65 mcg/m²
- Day 2: 125 mcg/m²
- Day 3: 250 mcg/m²
- Day 4: 500 mcg/m²
- Days 5 through 14: 1,030 mcg/m²

Coverage Period:

14-day treatment (1 treatment course per lifetime)

ICD-10:

R73.03

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Tzield (teplizumab-mzwv) Prescribing information. Provention Bio, Inc., Bridgewater, NJ: 4/2025
4. American Diabetes Association Professional Practice Committee for Diabetes*. 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes-2026. Diabetes Care. 2026 Jan 1;49(Supplement_1):S27-S49. doi: 10.2337/dc26-S002.
5. American Diabetes Association Professional Practice Committee for Diabetes*. 3. Prevention or Delay of Diabetes and Associated Comorbidities: Standards of Care in Diabetes-2026. Diabetes Care. 2026 Jan 1;49(Supplement_1):S50-S60. doi: 10.2337/dc26-S003.

Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- No clinical changes following routine annual review

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*