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.

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 for 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/m^2
- Day 2: 125 mcg/m^2
- Day 3: 250 mcg/m^2
- Day 4: 500 mcg/m^2
- Days 5 through 14: 1,030 mcg/m^2

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: 12/2023.

Review History

Date of Last Annual Review: 1Q2025
Changes from previous policy version:

- No clinical change following annual review.

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