Teplizumab-mzwv (Tzield™)	Place of Service Infusion Center Administration Office Administration Outpatient Facility Administration HCPCS: J3490, J3590 NDCs: 2 mg/2 mL vials 73650-0316-01 (1 single dose vial) 73650-0316-10 (10 single dose vial) 73650-0316-14 (14 single dose vial)

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

- Delaying the onset of stage 3 or clinical type 1 diabetes mellitus

AHFS therapeutic class: Antidiabetic Agent
Mechanism of action: CD3-directed humanized IgG1 kappa antibody

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Tzield™ (teplizumab-mzwv) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Delaying the onset of stage 3 or clinical type 1 diabetes mellitus

1. Prescribed by or in consultation with an endocrinologist, **AND**
2. Provider attestation the patient has family history for type 1 diabetes, **AND**
3. Patient is at least 8 years of age, **AND**
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, or
        ii. Insulin autoantibodies (IAA), or
        iii. Tyrosine phosphatase-like protein autoantibodies (IA-2, ICA512), or
        iv. Zinc transporter 8 autoantibody (ZnT8A), or
        v. Islet cell autoantibody (ICA)

    AND

    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, or
        ii. A 2-hour postprandial plasma glucose level between 140 and 199 mg/dL during an OGTT, or
        iii. An intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200 mg/dL on two occasions during an OGTT, or
        iv. Glycated hemoglobin (A1C) level between 5.7% and 6.4%

Covered Doses
Given by IV 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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Tzield™ (teplizumab-mzwv) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 2 mg per 2 mL (1 mg/mL) single-dose vial
    - 73650-0316-01 (1 single dose vial)
    - 73650-0316-10 (10 single dose vial)
    - 73650-0316-14 (14 single dose vial)

- Prior to initiating Tzield, administer all age-appropriate vaccinations as required, and obtain a complete blood count and liver enzyme tests.
- Premedicate prior to Tzield for the first 5 days of dosing with an NSAID or acetaminophen, antihistamine, and/or antiemetic
- Do not administer two doses on the same day.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Tzield™ (teplizumab-mzwv) [Prescribing information.] Red Bank, NJ: Provention Bio, Inc.; 11/2022.

(7) Policy Update

Date of initial review: 1Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- New policy