Medical Policy

Tzield™ (teplizumab-mzwv)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-132
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Tzield™ (teplizumab-mzwv) therapy.

POLICY

Tzield™ (teplizumab-mzwv) is not considered medically necessary due to insufficient evidence of therapeutic value. Teplizumab-mzwv does not meet the definition of medical necessity for all FDA approved indications including, but not limited to, treatment to delay the onset of Stage 3 Type 1 Diabetes in adults and pediatric patients at least 8 years of age with Stage 2 Type 1 Diabetes.

The current Tzield efficacy information is insufficient to determine if the medication demonstrates any clinically meaningful benefits. In the absence of additional clinical trials, there is not enough information to support approval.

LIMITATIONS/EXCLUSIONS

None

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Medical Policy

BACKGROUND

Teplizumab-mzwv is an FDA approved anti-CD3-directed antibody designed to bind CD3 antigens presented on the surface of T cells and delays procession to Stage 3 Type 1 Diabetes. The mechanism of action may involve partial agonistic signaling and deactivation of pancreatic beta cell autoreactive T cells. Teplizumab-mzwv is administered by intravenously (IV) infusion once daily for 14 consecutive days.

The efficacy of teplizumab-mzwv was studied in a randomized, double-blind, placebo-controlled phase 2 trial that included 76 patients between 8 to 49 years of age with Stage 2 Type 1 Diabetes. In this study, patients were randomized to receive teplizumab-mzwv or placebo once daily by IV infusion for 14 days. The primary endpoint was the time from randomization to development of Stage 3 Type 1 Diabetes diagnosis. The results of the study showed that 20 (45%) of the teplizumab-mzwv treated patients and 23 (72%) of the placebo treated patients were diagnosed with Stage 3 Type 1 Diabetes.

DEFINITIONS

1. TZIELD (teplizumab-mzwv) injection is a clear and colorless solution. TZIELD is supplied in single dose vials as follows:
    a. 2 mg per 2 mL (1 mg/mL) single-dose vial – NDC 73650-316-01
    b. 2 mg per 2 mL (1 mg/mL) 10 count single-dose vials – NDC 73650-316-10
    c. 2 mg per 2 mL (1 mg/mL) 14 count singe-dose vials – NDC 73650-316-14

CODING

Applicable NDC Codes	
73650-316-01	TZIELD (teplizumab-mzwv) injection 2mg per 2 mL (1 mg/mL) single- dose vial
73650-316-10	TZIELD (teplizumab-mzwv) injection 2mg per 2 mL (1 mg/mL) 10 count single-dose vials
73650-316-14	TZIELD (teplizumab-mzwv) injection 2mg per 2 mL (1 mg/mL) 14 count single-dose vials

Applicable Procedure Code	
C9399	Unclassified drug or biological (When utilized for Tzield [teplizumab-mzwv])
J3490	Unclassified drug (When utilized for Tzield [teplizumab-mzwv])
J3590	Unclassified biologics (When utilized for Tzield [teplizumab-mzwv])

Applicable ICD-10 Codes	
E10.8	Type 1 Diabetes mellitus with unspecified complications
E10.9	Type 1 Diabetes mellitus

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EVIDENCE BASED REFERENCES

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: December 28, 2022.
2. Tzield (teplizumab-mzwv) [prescribing information]. Red Bank, NJ: Provention Bio, Inc; December 2022.
3. Herold KC, Bundy BN, Long SA, et al; Type 1 Diabetes TrialNet Study Group. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. N Engl J Med. 2019 Aug 15;381(7):603-613. Available at: https://www.nejm.org/doi/10.1056/NEJMoa1902226. Accessed: December 21, 2022

POLICY HISTORY

Original Effective Date	02/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024

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