Tzield® (teplizumab-mzwv)
Injection | 2 mg/2mL

SAMPLE CODING

These codes are provided as examples only and are not all-inclusive; appropriate codes can vary by patient, setting of care, and payer. This guide is not meant to provide medical or legal advice or recommendations regarding the use of specific codes for billing purposes. The provider submitting the claim is responsible for determining the medical necessity, appropriate coding, and accuracy of claims.

TZIELD® (teplizumab-mzwv) is a CD3-directed monoclonal 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.

Type	Code	Description
Diagnosis: ICD-10-CM[1]	E10.9	Type 1 diabetes mellitus without complications
	E10.8	Type 1 diabetes mellitus with unspecified complications
Drug: HCPCS[2]	J9381	Injection, teplizumab-mzwv, 5 mcg*
Home infusion: HCPCS	S9329[3,†]	Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with S9330 or S9331)
	S9379[4]	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
Drug: NDC[5,‡]	73650-316-01	1 TZIELD (teplizumab-mzwv) 2 mg/2 mL, single-dose vial carton§
	73650-316-14	Pack of 14 TZIELD (teplizumab-mzwv) 2 mg/2 mL, single-dose vial cartons
	73650-316-10	Supplemental pack of 10 TZIELD (teplizumab-mzwv) 2 mg/2 mL, single-dose vial cartons
Administration procedures: CPT®[2]	96413[†]	Highly complex drugs, including biologic agents or chemotherapy administration, intravenous infusion technique up to 1 hour, single or initial substance/drug
	96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug) initial, up to 1 hour
	99601	Home infusion/specialty drug administration, per visit (up to 2 hours)

CPT = Current Procedural Terminology; FDA = US Food and Drug Administration; HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, 10th Revision, Clinical Modification; NDC = National Drug Code.

*Contact payers for specific coding requirements for billing wastage and modifiers.

†For payers who do not recognize TZIELD as approved for chemotherapy administration code 96413, other administration codes, such as 96365, may be used depending on individual payer policy.

‡Some payers may require an 11-digit NDC code. In such cases, add a 0 in front of the second set of numbers, eg, 73650-316-14 would become 73650-**0316**-14.

§This information is being provided for reimbursement coding purposes only. TZIELD is available to purchase directly from Cardinal Health Specialty Distribution in a pack of 14 single-dose vial cartons and a supplemental pack of 10 single-dose vial cartons. If a patient will be treated at more than one site of care and you need to discuss acquiring options other than these carton packs, contact Provention Bio COMPASS™ directly at 1-844-778-2246.

For more information, please refer to the **Billing & Coding Guide**.

Please read the full Important Safety Information on the next page.
Please see full Prescribing Information and Medication Guide.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Cytokine Release Syndrome (CRS):** CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. Prior to TZIELD treatment, premedicate with antipyretics, antihistamines and/or antiemetics, and treat similarly if symptoms occur during treatment. If severe CRS develops, consider pausing dosing for 1 day to 2 days and administering the remaining doses to complete the full 14-day course on consecutive days; or discontinue treatment. Monitor liver enzymes during treatment. Discontinue TZIELD treatment in patients who develop elevated alanine aminotransferase or aspartate aminotransferase more than 5 times the upper limit of normal (ULN) or bilirubin more than 3 times ULN.
- **Serious Infections:** Use of TZIELD is not recommended in patients with active serious infection or chronic infection other than localized skin infections. Monitor patients for signs and symptoms of infection during and after TZIELD administration. If serious infection develops, treat appropriately, and discontinue TZIELD.
- **Lymphopenia:** Lymphopenia occurred in most TZIELD-treated patients. For most patients, lymphocyte levels began to recover after the fifth day of treatment and returned to pretreatment values within two weeks after treatment completion and without dose interruption. Monitor white blood cell counts during the treatment period. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), discontinue TZIELD.
- **Hypersensitivity Reactions:** Acute hypersensitivity reactions including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in TZIELD-treated patients. If severe hypersensitivity reactions occur, discontinue TZIELD and treat promptly.
- **Vaccinations:** The safety of immunization with live-attenuated (live) vaccines with TZIELD-treated patients has not been studied. TZIELD may interfere with immune response to vaccination and decrease vaccine efficacy. Administer all age-appropriate vaccinations prior to starting TZIELD.
    - Administer live vaccines at least 8 weeks prior to treatment. Live vaccines are not recommended during treatment, or up to 52 weeks after treatment.
    - Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment. Inactivated vaccines are not recommended during treatment or 6 weeks after completion of treatment.

ADVERSE REACTIONS: Most common adverse reactions (>10%) were lymphopenia, rash, leukopenia, and headache.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm.
- **Lactation:** A lactating woman may consider pumping and discarding breast milk during and for 20 days after TZIELD administration.

Please see full Prescribing Information, including patient selection criteria, and Medication Guide.

Provention Bio does not make any representation or guarantee concerning reimbursement or coverage for any service or item. This guide is intended for informational purposes only and nothing included in this guide is intended, nor should be construed as, a guarantee of reimbursement or payment for any product or service.

References: 1. ICD10data.com. Type 1 diabetes mellitus E10. Accessed October 14, 2022. https://www.icd10data.com/ICD10CM/Codes/E00-E89/E08-E13/E10-. **2.** CMS. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations. Accessed May 10, 2023. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-1-2023-drugs-and-biologicals-updated-04/28/2023.pdf. **3.** HCPCS.Codes. Search results for S9329. https://hcpcs.codes/search/?q=S9329. Accessed October 14, 2022. **4.** HCPCS.Codes. Search results for S9379. Accessed October 14, 2022. https://hcpcs.codes/search/?q=S9379. **5.** TZIELD Prescribing Information. Provention Bio, a Sanofi Company.

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Tzield®
(teplizumab-mzwv)
Injection | 2mg/2mL