Tzield™ (teplizumab-mzwv)

Provention Bio COMPASS™

SAMPLE CODING

These codes 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 codes provided are examples only. The provider submitting the claim is responsible for determining medical necessity and appropriate coding, and for the submission of accurate claims.

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: temporary HCPCS[2]	J3490*	Unclassified drugs
	J3590*	Unclassified biologics
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,‡]	73650-316-14	Pack of 14 TZIELD (teplizumab-mzwv) 2 mg/2 mL, single-dose vial cartons
	73650-316-10	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.

*No permanent HCPCS code has been assigned for TZIELD. Therefore, you must currently use a miscellaneous code, either J3590 or J3490 on TZIELD claims. When submitting a claim with a miscellaneous J-code, make sure to include all pertinent information about the drug, including the full drug name and generic, dose, and route of administration. Payer requirements may vary. Check with individual payers on their requirements for the use of miscellaneous J-codes. Applicable codes may vary by site of care. Check with individual payers on their requirements.

†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.

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Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

CPT® is a registered trademark of the American Medical Association.

Please see Important Safety Information and Indication on the next page.
Before prescribing TZIELD, please read the accompanying Prescribing Information.
The Medication Guide is also available.

INDICATION

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.

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.

Before prescribing TZIELD, please read the accompanying Prescribing Information.
The Medication Guide is also available.

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.** American Academy of Professional Coders. Codify. Accessed October 14, 2022. https://www.aapc.com/codes. **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, Inc.

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