

BILLING AND CODING GUIDE

TZIELD[®] (teplizumab-mzwv) J-code: J9381

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.

OVERVIEW OF THIS GUIDE

This guide has been developed to provide sample coding and billing information to assist you in obtaining insurance reimbursement for TZIELD. The information within this guide reviews some of the codes commonly associated with the administration of TZIELD. However, your office should check directly with the patient's insurance plan to verify coding recommendations.

The codes included in this guide are not all-inclusive; appropriate codes can vary by patient, setting of care, and payer. Codes provided in this guide may be subject to change.

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.

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.

ACCESSING TZIELD¹

SITE OF SERVICE

TZIELD is administered by intravenous (IV) infusion (over a minimum of 30 minutes) once daily for 14 consecutive days. Depending on your patient's insurance coverage, you and your patient can evaluate which of the following locations is appropriate for their treatment. Options could include: a doctor's office, a hospital, an infusion center, or their home with a nurse.

For most payers, the site(s) of service will affect the coding and billing requirements. Infusion scenarios may include:

1. Daily outpatient infusions on each of the 14 days in a doctor's office, a hospital, an infusion center, or other healthcare facility
2. At-home infusion on each of the 14 days
3. A hybrid model that begins with outpatient infusions and transitions to at-home infusions for a total of 14 days

HOW TO ORDER TZIELD

- TZIELD is available to purchase from Cardinal Health Specialty Pharmacy Distribution for buy-and-bill treatment centers and through a limited network of specialty pharmacies
- TZIELD is available in a pack of 14 single-dose vial cartons through Cardinal Health Specialty Distribution. A supplemental pack of 10 single-dose vial cartons is available for patients requiring treatment with 24 vials due to body surface area-based dosing requirements. 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.

BUY AND BILL

Cardinal Health	P: 1-855-740-1867	GMB-SPD-MFGSERVICESSP@cardinalhealth.com
Cardinal Health Puerto Rico	P: 1-787-625-4398 F: 787-625-4200	cuserv@cardinalhealth.com

Do you want to establish a new account with Cardinal Health Specialty Distribution?
Call 1-866-677-4844 to set up a new account.

LIMITED NETWORK SPECIALTY PHARMACIES

Amber™ Specialty Pharmacy	P: 1-888-370-1724 F: 877-274-4329
Hy-Vee® Pharmacy Solutions	P: 1-877-794-9833 F: 877-274-4329
Orsini® Specialty Pharmacy	P: 1-800-670-5321 F: 877-655-4364

DOSAGE AND NATIONAL DRUG CODE (NDC) DESIGNATION FOR TZIELD¹

TZIELD injection is supplied as a sterile, preservative-free, clear and colorless solution in a 2 mg/2 mL (1 mg/mL) single-dose vial for intravenous use. Each mL contains 1 mg teplizumab-mzwv, dibasic sodium phosphate (0.26 mg), monobasic sodium phosphate (0.98 mg), polysorbate 80 (0.05 mg), sodium chloride (8.78 mg), and water for injection. The dose is calculated based on body surface area (BSA) administered over 14 consecutive days.

DOSING REGIMEN				
Day 1	Day 2	Day 3	Day 4	Days 5-14
65 mcg/m ²	125 mcg/m ²	250 mcg/m ²	500 mcg/m ²	1030 mcg/m ²

TZIELD is supplied as a clear and colorless solution in one 2 mg/2 mL, single-dose vial

CALCULATION

How to calculate BSA using the Mosteller formula²:

BSA Equation:

$$BSA (m^2) = \sqrt{\frac{[\text{height (cm)} \times \text{weight (kg)}]}{3600}}$$

Example: Male, 8 years old = 120 cm, 26 kg

$$BSA (m^2) = \sqrt{\frac{(120)(26)}{3600}} = 0.931 m^2$$

Based on BSA dosing requirements, 2 vials may be needed for some individuals for doses 5-14 (BSA > 1.94).

NDC numbers for TZIELD

NDC Number*	Description
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
73650-316-01	1 TZIELD (teplizumab-mzwv) 2 mg/2 mL, single-dose vial carton [†]

*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.

NDC = National Drug Code.

Payer requirements regarding the use of the 10- or 11-digit NDC may vary.
Check payer requirements for appropriate reporting of the NDC.

SAMPLE CODES

The following codes may be useful when coding and billing for TZIELD infusion. **Please note that these codes do not include office visits for diagnosis and prescribing of medication.**

ICD-10-CM diagnosis codes³

A diagnosis of type 1 diabetes in Stage 2 patients is required to substantiate the medical necessity of TZIELD. The following codes may be relevant when documenting a patient's diagnosis.

Condition	Code
Type 1 diabetes mellitus without complications	E10.9
Type 1 diabetes mellitus with unspecified complications	E10.8

HCPCS Code for TZIELD⁴

TZIELD is billed under an HCPCS J-code. Effective July 1, 2023, the Centers for Medicare & Medicaid Services assigned TZIELD the following permanent J-code: J9381.

Description	Code
Injection, teplizumab-mzwv, 5 mcg	J9381

When billing for TZIELD with HCPCS code J9381, 1 unit represents 5 mcg of TZIELD. TZIELD should be billed based on units, not the number of milligrams.

Utilization of the J-code is required when billing for TZIELD. Please ensure the billing system at your organization has been updated accordingly to support accurate coding and billing processes.

HCPCS Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payers with additional information regarding the services rendered. If appropriate, more than 1 modifier may be used with a single procedure code.

Certain payers require the "JW" modifier to be used in order to obtain payment for a discarded amount of drug for single-dose or single-use packaging. For claims submitted with J9381, providers should use multiple lines to identify the amount administered and the amount wasted. One line of the claim should include J9381 and number of units administered. A separate line should included J9381 with the JW modifier and the number of unites wasted.

Effective January 1, 2023, modifier "JZ" may be reported on claims to note zero discarded amounts from single use vials or single use packages. CMS will require the reporting of modifier JZ effective July 1, 2023. Claims processing edits will be implemented by the MACs effective October 1, 2023.

Modifier	Description	Appropriate Use
JW	Drug amount discarded/not administered to any patient	Append to J9381 when there was discarded drug amount
JZ	Zero drug amount discarded/not administered to any patient	Append to J9381 when there was NO discarded drug amount

HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, 10th Revision, Clinical Modification.

Please see Important Safety Information continued on page 12 and full [Prescribing Information](#), including [Medication Guide](#).

SAMPLE CODES (cont.)

Administration procedure CPT[®] codes³

Description	Code
IV infusion, for therapy, prophylaxis, or diagnosis; initial, up to one hour	96365
Highly complex drugs, including biologic agents or chemotherapy administration, intravenous infusion technique up to 1 hour, single or initial substance/drug	96413*
Home infusion/specialty drug administration, per visit (up to 2 hours)	99601

Home infusion HCPCS codes

Description	Code
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) ⁵	S9329*
Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment ⁶	S9379

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*TZIELD is an anti-CD3, humanized, monoclonal antibody.¹ TZIELD is not chemotherapy, however, some payers may utilize these codes in the reimbursement process. 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.

CD3 = cluster of differentiation 3; CPT = Current Procedural Terminology.

SAMPLE CODES FOR TESTING

ICD-10-CM codes for T1D-related pancreatic islet autoantibody testing⁴

Description	Code
Diagnosis for type 1 diabetes	E10.1-E10.9
Encounter for screening for diabetes mellitus	Z13.1
Family history of diabetes mellitus	Z83.3
Family history of other endocrine, nutritional, and metabolic diseases	Z83.49
Endocrine disorder, unspecified	E34.9

CPT codes for T1D-related pancreatic islet autoantibody immunoassays⁴

Description	Code
Glutamic acid decarboxylase 65 (GAD) autoantibodies	86341
Insulinoma-associated antigen 2 autoantibody (IA-2A)	
Zinc transporter 8 antibody (ZnT8A)	
Islet cell antibody (ICA)	
Insulin antibody (IAA)	86337

CPT codes for measuring dysglycemia⁴

Confirmation of dysglycemia without overt hyperglycemia, using an oral glucose tolerance test, is recommended; if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate.

Description	Code
Glucose tolerance test (GTT), 3 specimens (includes glucose)	82951
Glucose; quantitative, blood (except reagent strip)	82947
Glucose post glucose dose (includes glucose)	82950
Hemoglobin glycosylated (A1C)	83036

CPT codes related to monitoring¹

Prior to initiating TZIELD, obtain a complete blood count and liver enzyme tests. Monitor liver enzymes and white blood cell counts during treatment. Discontinue TZIELD treatment in patients who develop elevated ALT or AST more than 5 times the upper limit of normal (ULN), or bilirubin more than 3 times ULN, or prolonged severe lymphopenia (<500 cells per mL lasting 1 week or longer).

Test	Code
AST value test ⁴	84450*
ALT value test ⁴	84460*
Complete blood count ³	85027*

*A specific test code may be required in addition to the CPT code. Please confirm which codes are required for your preferred laboratory.

ALT = alanine transaminase; AST = aspartate aminotransferase; FDA = US Food and Drug Administration.

Please see Important Safety Information continued on page 12 and full [Prescribing Information](#), including [Medication Guide](#).

SAMPLE CMS-1500 FORM

The CMS-1500 form is used to submit claims for TZIELD in non-institutional (physician office) settings.

The highlighted sections and table below discuss key information to include when submitting a claim for TZIELD.

When billing for TZIELD with HCPCS code J9381, 1 unit represents 5 mcg of TZIELD. For example, 1 (2mg/mL) vial = 400 units. TZIELD should be billed based on units, not the number of micrograms.

CMS-1500	INFORMATION TO BE INCLUDED	FIELD DESCRIPTION
BOX 17	Indicate the appropriate provider to the dotted line in box 17 and indicate your NPI in 17b	Provider information
BOX 19	Indicate pertinent information about the drug, including the full drug name and generic (TZIELD [teplizumab-mzww]), dose, and route of administration	Additional information
BOX 21	Indicate ICD diagnosis code as reflected in the patient's medical record ICD-10 code (example: E10.8 or E10.9, diagnosis for type 1 diabetes)	Diagnosis or nature of illness of injury
BOX 23	The payer-assigned number authorizing the service(s)	Prior authorization number
BOX 24A	Date of service	Shaded box
BOX 24D	Enter the appropriate HCPCS (J9381) and CPT® codes. Include any additional modifiers required by the payer (eg, to indicate wastage). See page 5 of this guide for more information about using modifiers	Procedures, services, or supplies
BOX 24G	Document the number of units used for each line item. When billing for TZIELD with HCPCS code J9381, 1 unit represents 5 mcg of TZIELD. TZIELD should be billed based on units, not the number of micrograms	Units
BOX 29	Indicate the amount paid by the patient	Patient cost collected

For informational purposes only. Check with individual payers for specific requirements. NPI = National Provider Identifier.

Please see Important Safety Information continued on page 12 and full Prescribing Information, including Medication Guide.

SAMPLE CMS-1450 FORM

CMS-1450, or UB-04, is the form used to submit claims for TZIELD in an institutional setting such as a hospital outpatient department.

The highlighted sections and table below discuss key information to include when submitting a claim for TZIELD.

When billing for TZIELD with HCPCS code J9381, 1 unit represents 5 mcg of TZIELD. For example, 1 (2mg/mL) vial = 400 units. TZIELD should be billed based on units, not the number of micrograms.

CMS-1450	INFORMATION TO BE INCLUDED
BOX 4	Enter the appropriate type of bill code; for example <ul style="list-style-type: none"> • 013X, Hospital outpatient • 014X, Hospital other Part B
BOX 38	Enter the name and address of the person responsible for the bill
BOXES 42 & 43	Enter the appropriate revenue code and description corresponding to the HCPCS code listed in Box 44. Confirm with the payer how NDC numbers should be noted on the claim form
BOX 44	Use the permanent HCPCS code for TZIELD (J9381)
BOX 46	Document the number of units used for each line item. When billing for TZIELD with HCPCS code J9381, 1 unit represents 5 mcg of TZIELD. TZIELD should be billed based on units, not the number of micrograms
BOX 56	Indicate your NPI
BOX 63	Indicate the prior authorization number here
BOX 67	Enter the appropriate ICD-10 diagnosis code that corresponds to the patient's diagnosis (example: E10.8 or E10.9, diagnosis for type 1 diabetes)

For informational purposes only. Check with individual payers for specific requirements.

Please see **Important Safety Information** continued on page 12 and full [Prescribing Information](#), including [Medication Guide](#).

FREQUENTLY ASKED QUESTIONS

INSURANCE

1. HOW CAN I ORDER TZIELD?

TZIELD is available to purchase from Cardinal Health Specialty Distribution for buy-and-bill treatment centers and through a limited network of specialty pharmacies composed of Amber Specialty Pharmacy, including Hy-Vee Pharmacy Solutions, and Orsini Specialty Pharmacy.

TZIELD is available in a pack of 14 single-dose vial cartons through Cardinal Health Specialty Distribution. A supplemental pack of 10 single-dose vial cartons is available for patients requiring treatment with 24 vials due to body surface area-based dosing requirements. 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.

2. IS TZIELD COVERED UNDER AN INPATIENT DIAGNOSIS-RELATED GROUP (DRG) FOR BILLING?

TZIELD is intended to be administered in an outpatient setting and is therefore not expected to be reimbursed through DRG payment structures. Please contact the patient's health plan as needed for additional clarity.

3. WILL TZIELD BE COVERED UNDER THE MEDICAL BENEFIT OR PHARMACY BENEFIT?

Health plans typically cover TZIELD under the medical benefit. Please check with your patient's health plan.

4. HOW DO I BILL FOR TZIELD THROUGH STATE MEDICAID?

Each Medicaid plan will vary in their coverage policies. Please contact your Provention Bio COMPASS Navigator for additional information regarding the applicable Medicaid coverage policies or contact the applicable Medicaid plan.

5. HOW DOES INSURANCE REIMBURSE FOR INFUSION OF TZIELD?

Typically, the cost of TZIELD would be billed separately from services related to its infusion for buy-and-bill treatment centers. Please check with your patient's health plan, and refer to the CPT codes in this guide for more information that will help you when billing for infusion of TZIELD.

6. HOW DO I SUBMIT A CLAIM FOR AN INFUSION OF TZIELD WHEN I DID NOT PURCHASE THE DRUG?

If you have received TZIELD at no cost (for example, through a specialty pharmacy), you may not bill third-party payers for it. Although you may not bill for the drug, you may be able to bill for the administration service. Some payers may require you to enter a J-code on the claim form with a zero charge to identify which drug was administered. To verify if there are special billing guidelines for a drug obtained at no charge, it is important to check with the specific payer.

7. WHAT HAPPENS IF MY CLAIM IS DENIED?

If the health insurance plan denies your claim, you may file an appeal. Confirm the reason for the denial in the documentation from the health plan and address any required revisions to the claim through the health plan's appeal process. For more information, call Provention Bio COMPASS at 1-844-778-2246, Monday through Friday, 8 AM-8 PM ET or visit <https://tzielhcp.com/patient-support>.

*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.

FREQUENTLY ASKED QUESTIONS (cont.)

PROVENTION BIO COMPASS™ COPAY PROGRAM

8. WHAT IS THE PROVENTION BIO COPAY PROGRAM?

With the Provention Bio Copay Program,* commercially or privately insured individuals may pay as little as \$0 for TZIELD. If your patient qualifies, their COMPASS Navigator can help enroll them into the program so they may be able to lower their out-of-pocket costs.

This program is intended to help patients with the cost of TZIELD and its infusion administration only. It does not help with the cost of other medicines your patients take at the same time as TZIELD or with other facility fees.

*Eligibility requirements and terms and conditions apply. See <https://tzielhcp.com/pdf/compass-program-terms-and-conditions.pdf> for more information.

9. HOW CAN MY PATIENT ENROLL IN THE PROVENTION BIO COPAY PROGRAM?

To enroll your patient in Provention Bio COMPASS,† you will each fill out a section of the START Form. Once completed, you can submit it to enroll your patient in the program.

If your patient qualifies, their COMPASS Navigator can help enroll them in the copay program.

This program is intended to help your patient with the cost of TZIELD and its infusion administration only. It does not help with the cost of other medicines your patients take at the same time as TZIELD or with other facility fees.

†Provention Bio COMPASS is a patient support program that helps patients to gain access to TZIELD and provides patients with education and resources related to TZIELD. Provention Bio COMPASS is not a healthcare service or an insurance provider and does not provide care coordination. Provention Bio COMPASS and the COMPASS Navigator will not provide medical or treatment advice. Provention Bio COMPASS services are available only to those who have been prescribed TZIELD and are intended for US residents only.

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 mL 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 the accompanying [Prescribing Information](#). The [Medication Guide](#) is also available.

FOR MORE INFORMATION OR QUESTIONS ABOUT BILLING & CODING FOR TZIELD



CALL
Provention Bio COMPASS™ at
1-844-778-2246 Monday through Friday,
8 AM-8 PM ET



EMAIL
COMPASS@proventionbio.com



FAX
908-425-4840



VISIT
<https://tzieldhcp.com/patient-support>

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