

# CODING AND BILLING INFORMATION FOR TZIELD<sup>™</sup> (teplizumab-mzwv)

## CONSIDERATIONS FOR TZIELD CLAIMS SUBMISSIONS

### INDICATION

TZIELD<sup>™</sup> (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.

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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 TZIELD<sup>1</sup>

### 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 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 and in a pack of 10 single-dose vial cartons through Cardinal Health Specialty Distribution. 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<sup>™</sup> directly at 1-844-778-2246 Monday through Friday, 8 AM-8 PM ET

#### BUY AND BILL

Cardinal Health

P: 1-855-740-1867

GMB-SPD-MFGSERVICESSP@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 TZIELD<sup>1</sup>

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
<b>65</b> mcg/m <sup>2</sup>	<b>125</b> mcg/m <sup>2</sup>	<b>250</b> mcg/m <sup>2</sup>	<b>500</b> mcg/m <sup>2</sup>	<b>1030</b> mcg/m <sup>2</sup>

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 formula<sup>2</sup>:

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.

### 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	Pack of 10 TZIELD (teplizumab-mzwv) 2 mg/2 mL, single-dose vial cartons

\*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.

NDC = National Drug Code.

When submitting a claim for TZIELD, be sure to indicate the total number of vials administered to your patient

## 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 codes<sup>3</sup>

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

### Drug HCPCS codes<sup>4</sup>

Currently, there is no permanent J-code available for TZIELD. The following miscellaneous J-codes may be applicable until a permanent J-code for TZIELD is available.

Description	Code
Unclassified biologics	J3590
Unclassified drugs	J3490

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.

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

## SAMPLE CODES (cont.)

### Administration procedure CPT<sup>®</sup> codes<sup>3</sup>

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

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\*TZIELD is an anti-CD3, humanized, monoclonal antibody.<sup>1</sup> 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 codes for T1D-related pancreatic islet autoantibody screening<sup>4</sup>

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 immunoassays<sup>4</sup>

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 dysglycemia<sup>4</sup>

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 monitoring<sup>1</sup>

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 <sup>4</sup>	84450*
ALT value test <sup>4</sup>	84460*
Complete blood count <sup>3</sup>	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.

# 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 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.

The image shows a sample CMS-1500 Health Insurance Claim Form. Red boxes highlight specific areas: Box 17 (Referring Provider), Box 19 (Additional Claim Information), Box 21 (Diagnosis), Box 23 (Prior Authorization Number), Box 24A (Date of Service), Box 24D (Procedure, Service, or Supplier), Box 24G (Units), and Box 29 (Amount Paid). The form includes fields for patient information, insurance details, dates, and provider information.

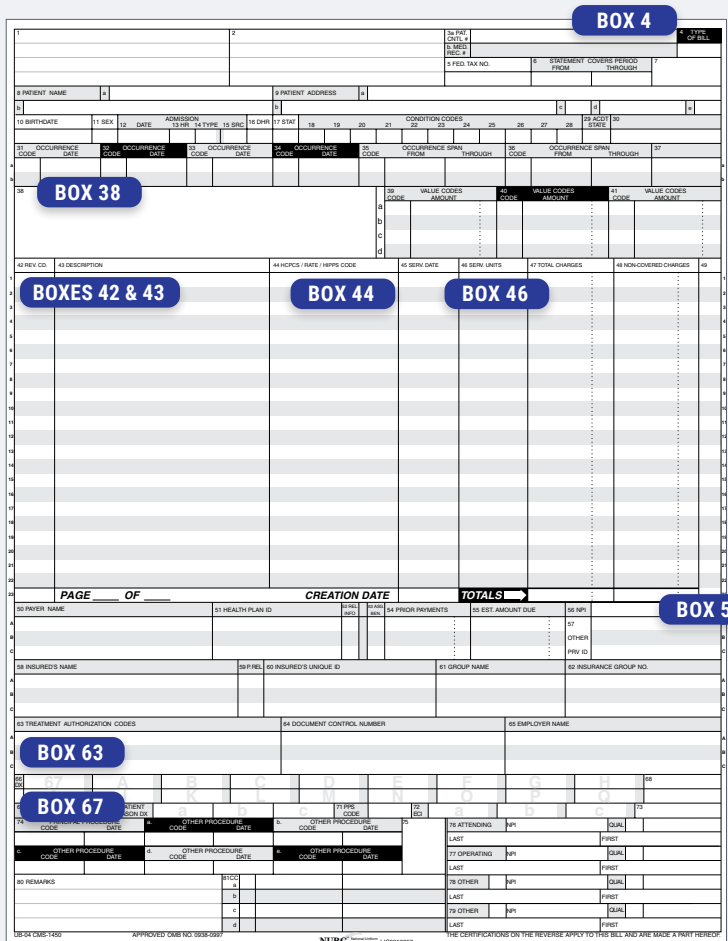
CMS-1500	INFORMATION TO BE INCLUDED	FIELD DESCRIPTION
<b>BOX 17</b>	Indicate the appropriate provider to the dotted line in box 17 and indicate your NPI in 17b	Provider information
<b>BOX 19</b>	Indicate pertinent information about the drug, including the full drug name and generic (TZIELD [teplizumab-mzwv]), dose, and route of administration	Additional information
<b>BOX 21</b>	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
<b>BOX 23</b>	The payer-assigned number authorizing the service(s)	Prior authorization number
<b>BOX 24A</b>	Date of service	Shaded box
<b>BOX 24D</b>	Product Use a temporary HCPCS code for TZIELD (examples: J3590, J3490) Related Administration Procedure Determine appropriate product administration CPT code	Procedures, services, or supplies
<b>BOX 24G</b>	Indicate 1 unit for each vial TZIELD is supplied in one 2 mg/2 mL, single-dose vial	Units
<b>BOX 29</b>	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 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.

CMS-1450	INFORMATION TO BE INCLUDED
<b>BOX 4</b>	Enter the appropriate type of bill code; for example <ul style="list-style-type: none"> <li>• 013X, Hospital outpatient</li> <li>• 014X, Hospital other Part B</li> </ul>
<b>BOX 38</b>	Enter the name and address of the person responsible for the bill
<b>BOXES 42 &amp; 43</b>	Enter appropriate revenue code and description of service, including the full drug name and generic (TZIELD [teplizumab-mzwv]), dose, and route of administration
<b>BOX 44</b>	Use a temporary HCPCS code for TZIELD (examples: J3590, J3490)
<b>BOX 46</b>	Enter the number of units administered. Indicate 1 unit for each vial TZIELD is supplied in one 2 mg/2 mL, single-dose vial
<b>BOX 56</b>	Indicate your NPI
<b>BOX 63</b>	Indicate the prior authorization number here
<b>BOX 67</b>	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, NDC: 73650-316-14,\* and in a pack of 10 single-dose vial cartons, NDC: 73650-316-10, through Cardinal Health Specialty Distribution.<sup>1</sup> If a patient will be treated in 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 Monday through Friday, 8 AM-8 PM ET.

#### 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://tzielhdcp.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://tziieldhcp.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.

## INDICATION

TZIELD™ (teplizumab-mzww) 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 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.

Before prescribing TZIELD, please read the accompanying [Prescribing Information](#). The [Medication Guide](#) is also available.

### FOR MORE INFORMATION OR QUESTIONS ABOUT DOSING AND ADMINISTRATION 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://tzielhcp.com/patient-support>**

**References:** **1.** TZIELD Prescribing Information. Provention Bio, Inc. **2.** Mosteller RD. Simplified calculation of body-surface area. *N Engl J Med.* 1987;317(17):1098. doi: 10.1056/NEJM198710223171717. **3.** ICD10data.com. Type 1 diabetes mellitus E10. Accessed October 14, 2022. <https://www.icd10data.com/ICD10CM/Codes/E00-E89/E08-E13/E10-> **4.** American Academy of Professional Coders. Codify. Accessed October 14, 2022. <https://www.aapc.com/codes>. **5.** HCPCS.Codes. Search results for S9329. <https://hcpcs.codes/search/?q=S9329>. Accessed October 14, 2022. **6.** HCPCS.Codes. Search results for S9379. Accessed October 14, 2022. <https://hcpcs.codes/search/?q=S9379>. Provention Bio and the Provention Bio logo are the registered trademarks of Provention Bio, Inc. TZIELD and Provention Bio COMPASS are the trademarks of Provention Bio, Inc. Third party marks ® and ™ are the property of their respective owners.

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