NOW APPROVED EXPANDED PEDIATRIC INDICATION
in children as young as 1 year of age with Stage 2 T1D

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

Formulary Kit

For appropriate patients with Stage 2 type 1 diabetes (T1D)

Intended for use with population health decision makers, including formulary committees, pharmacy and therapeutics committees, medical advisory boards, medical directors, and other individuals or entities who have responsibility for the selection of drugs, pursuant to FD&C Act Section 502(a).

INDICATION

TZIELD (teplizumab-mzwv) is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 1 year of age and older with Stage 2 T1D.

IMPORTANT SAFETY INFORMATION

WARNING: Viral Reactivation

- **Serious, life-threatening cases of viral reactivation, including Epstein-Barr virus (EBV) and cytomegalovirus (CMV) reactivation have been reported with TZIELD. Patients who are immunocompromised are at increased risk. The majority of serious cases occurred in patients who continued TZIELD treatment despite persistent, severe lymphopenia.**
- **Test patients for active EBV and CMV infection prior to starting treatment. TZIELD is not recommended in patients with laboratory or clinical evidence of active EBV or CMV infection. Adhere to lymphocyte count monitoring requirements and discontinuation recommendations. Monitor patients for signs and symptoms of viral reactivation following TZIELD treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD.**

Please see Important Safety Information throughout and see full Prescribing Information, including Boxed Warning and patient selection criteria.

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EHR = electronic health record; IV = intravenous.

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

Clinical Data

Product Profile[1]

Indication

TZIELD (teplizumab-mzwv) is indicated to delay the onset of Stage 3 T1D in adults and pediatric patients 1 year of age and older with Stage 2 T1D.

Description/Mechanism of Action

TZIELD binds to CD3 (a cell surface antigen present on T lymphocytes) and delays the onset of Stage 3 T1D in adult and pediatric patients aged 1 year and older with Stage 2 T1D. The mechanism may involve partial agonistic signaling and deactivation of pancreatic beta-cell autoreactive T lymphocytes. TZIELD leads to an increase in the proportion of regulatory T cells and of exhausted CD8+ T cells in peripheral blood.

Patient Selection

Select adult and pediatric patients 1 year of age and older with Stage 2 T1D for TZIELD treatment to delay the onset of Stage 3 T1D based on the confirmation of

- At least two positive pancreatic islet cell autoantibodies, and
- Dysglycemia without overt hyperglycemia using an oral glucose tolerance test (if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate)

Ensure the patient's diagnosis confirms an autoimmune origin and does not suggest type 2 diabetes or other forms of diabetes. These may include, but are not limited to, genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), or diabetes secondary to medications or surgery.

CD3 = cluster of differentiation 3; CD8 = cluster of differentiation 8.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Viral Reactivation: Serious, life-threatening cases of viral reactivation, including EBV and CMV have been reported with TZIELD. During and within 2 months of TZIELD treatment, if primary infection or reactivation of EBV or CMV occurs, it may present with increased severity, including EBV-associated lymphoproliferative disease and organ failure. Patients who are immunocompromised, including patients with Down syndrome, may be at increased risk. The majority of serious viral reactivation cases occurred in patients who continued TZIELD despite persistent, severe lymphopenia. Prior to initiating treatment with TZIELD, evaluate patients for active EBV and CMV infection and confirm undetectable viral load (e.g., PCR testing). TZIELD is not recommended in patients with laboratory or clinical evidence of active EBV or CMV infection. During treatment with TZIELD, regularly monitor lymphocyte counts and monitor patients for signs and symptoms of viral reactivation during treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD and obtain viral load (e.g., PCR) promptly. If viral reactivation is confirmed, permanently discontinue TZIELD.

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

Clinical Data (cont'd)

Stage 2 (TN-10) Study[1]

TN-10 Study Design

The safety and efficacy of TZIELD in the treatment of patients 8 to 49 years of age with Stage 2 T1D was investigated in Study TN-10.

TN-10 study design	A randomized, double-blind, event-driven, placebo-controlled study
Treatment regimen	Patients were randomized to receive TZIELD or placebo once daily by intravenous infusion for 14 days. Patients in the TZIELD group had a total drug exposure that was comparable to the total drug exposure achieved with the recommended total TZIELD dosage
Eligible patients	• 76 patients 8 to 49 years of age with Stage 2 T1D • Stage 2 T1D was defined as having both of the following – Two or more of the following pancreatic islet autoantibodies • Glutamic acid decarboxylase 65 (GAD) autoantibodies • Insulin autoantibody (IAA) • Insulinoma-associated antigen 2 autoantibody (IA-2A) • Zinc transporter 8 autoantibody (ZnT8A) • Islet cell autoantibody (ICA) – Dysglycemia on oral glucose tolerance testing • In this study, 45% were female; 97% White, 1% Asian, and 1% reported multiracial background; 3% were Hispanic or Latino ethnicity; and 95% were from the United States. The median age was 14 years (72% were <18 years old)
Primary endpoint	Median time from randomization to development of Stage 3 T1D diagnosis

TN-10 Study Efficacy Results

- In Study TN-10, Stage 3 T1D was diagnosed in 20 (45%) of the patients treated with TZIELD and in 23 (72%) of the placebo-treated patients
- A Cox proportional hazards model, stratified by age and oral glucose tolerance test status at randomization, demonstrated that the median time from randomization to Stage 3 T1D diagnosis was 50 months in the TZIELD group and 25 months in the placebo group, for a difference of 25 months
- With a median follow-up time of 51 months, therapy with TZIELD resulted in a statistically significant delay in the development of Stage 3 T1D (hazard ratio, 0.41; 95% CI: 0.22 to 0.78; p=.0066)
- Study TN-10 was not designed to assess whether there were differences in the effectiveness between subgroups based on demographic characteristics or baseline disease characteristics

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Cytokine Release Syndrome (CRS): CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. CRS manifestations in TZIELD-treated patients included fever, nausea (with or without vomiting), fatigue, headache, myalgia, arthralgia, increased ALT, increased AST, and increased total bilirubin. These manifestations typically occurred during the first 5 days of TZIELD treatment. 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.

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Clinical Data (cont'd)

Stage 2 (TN-10) Study[1] (cont'd)

TN-10 Adverse Events

The table below presents common (≥ 5%) adverse reactions that occurred during treatment and through 28 days after the last study drug administration in Study TN-10. Adverse reactions observed in pediatric patients 8 years and older who received TZIELD were consistent with those reported in adult patients in this study.

Common adverse reactions in adult and pediatric patients 8 years of age and older in the TN-10 study*,†

Adverse reactions	Placebo (n=32)	TZIELD (n=44)
Lymphopenia	6%	73%
Rash‡	0%	36%
Leukopenia	0%	21%
Headache	6%	11%
Neutropenia	3%	5%
Increased alanine aminotransferase	3%	5%
Nausea	3%	5%
Diarrhea	0%	5%
Nasopharyngitis	0%	5%

The approval of TZIELD was supported by a pooled safety analysis spanning 5 clinical studies, including 773 patients (44 patients with Stage 2 T1D and 729 patients from an unapproved population)[1,§]

Serious Adverse Reactions[1]

Throughout the study, greater incidences of these serious adverse reactions were reported in TZIELD-treated patients vs placebo-treated patients

- Cytokine release syndrome (2% vs 0%)
- Serious infections‖ (9% vs 0%)
- Lymphopenia (73% vs 6%)
- Hypersensitivity reactions and serum sickness (2% vs 0%)

*Adverse reactions that occurred in 2 or more TZIELD-treated patients.
†Adverse reactions that occurred during treatment and through 28 days after the last study drug administration.
‡Composite of rash-related terms, including rash erythematous, rash macular, rash papular, rash maculo-papular, and rash pruritic.
§In these studies, 436 patients received a 14-day dosing regimen of TZIELD with a total drug exposure comparable to the recommended approved dosage (Study TN-10), 168 patients received a 14-day course of TZIELD with a lower total TZIELD drug exposure, and 169 patients received a 6-day course of TZIELD with a lower total TZIELD drug exposure.
‖Serious infections included cellulitis, gastroenteritis, pneumonia, and wound infection any time during or after the first dose of study treatment.

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Clinical Data (cont'd)

Stage 2 (PETITE-T1D) Study[1]

PETITE-T1D Study Design

The safety of TZIELD was evaluated in a nonrandomized, single-arm, open-label, multicenter study in 23 pediatric patients age 1 to younger than 8 years with Stage 2 T1D.

Patient characteristic		TZIELD (n=23)
Patients completing 14-day course, %		87
Age at Day 1, years	Median	4.9
	Min, max	1.7, 6.8
Age distribution, %	<2	4.3
	2 to <5	52
	5 to <8	44
Race, %	White	96
	Asian	4
	Hispanic/Latino	13
First-degree relatives with T1D, %		87
Positive for ≥3 islet AAbs, %		87
AAb distribution, %	IAA	87
	ICA	85
	GAD	83
	ZnT8	74
	IA-2A	68
HbA1c at baseline	Median	5.5

PETITE-T1D Adverse Events

- Overall, the safety profile of TZIELD observed in pediatric patients younger than 8 years of age with Stage 2 T1D was consistent with that observed in patients aged 8 years and older with Stage 2 T1D
- The most common adverse reactions that occurred in patients younger than 8 years of age were
  - Diarrhea (30%)
  - Vomiting (52%)
- Procedure Related Venous Thrombosis: One teplizumab-treated patient (4.3%) in the PETITE-T1D study experienced a deep vein thrombosis

AAb = autoantibody; HbA1C = glycated hemoglobin.

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

Dosing and Administration

Recommended Dosage and Administration[1]

TZIELD is administered by intravenous infusion, over a minimum of

- 30 minutes in adult and pediatric patients aged 8 years and older[1]
- 2 hours in pediatric patients aged 1 to less than 8 years[1]

Dosing Regimen: Calculate the dosage using BSA and administer TZIELD once daily for 14 consecutive days as follows

Day	1	2	3	4	5-14
Dose mcg/m^2	65	125	250	**500**	**1030**

How to calculate BSA using the Mosteller formula[2]:

BSA Equation:

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

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

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

Administration Supplies for TZIELD May Include EITHER

- One or 2 (depending on calculated dose*) sterile glass vial(s) with 18 mL of 0.9% Sodium Chloride Injection, or
- One or 2 (depending on calculated dose*) ≤50 mL PVC with DEHP infusion bag(s) with 18 mL of 0.9% Sodium Chloride Injection
- Appropriately sized syringe
- IV catheter
- Routine infusion supplies (eg, needles, gauze, tape, alcohol wipes, tourniquet, etc)

For additional information on dosing and administration of TZIELD, scan the QR code or click here.

*Calculated doses of ≤2000 mcg require 1 sterile glass vial or PVC with DEHP infusion bag. Calculated doses of >2000 mcg require 2 sterile glass vials or PVC with DEHP infusion bags.
BSA = body surface area; DEHP = Di-2-ethylhexyl phthalate; PVC = polyvinyl chloride.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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

Dosing and Administration (cont'd)

Preparing TZIELD for IV Infusion[1]

Preparation Instructions

Using the dose calculated according to BSA, dilute TZIELD prior to preparing the infusion according to the instructions below.

TZIELD Dilution Preparation

- Prior to dilution, inspect TZIELD visually before use (the supplied solution is clear and colorless). Do not use TZIELD if particulate matter or coloration is seen
- Prepare TZIELD using aseptic technique
- If the calculated dose is
  - 2000 mcg or less, then prepare
    - **One** sterile glass vial with 18 mL of 0.9% Sodium Chloride Injection **or**
    - **One** ≤50 mL PVC with DEHP infusion bag with 18 mL of 0.9% Sodium Chloride Injection
  - Greater than 2000 mcg, then prepare
    - **Two** sterile glass vials with 18 mL of 0.9% Sodium Chloride Injection **or**
    - **Two** ≤50 mL PVC with DEHP infusion bags with 18 mL of 0.9% Sodium Chloride Injection
- Remove 2 mL of TZIELD from the single-dose vial and slowly add to the glass vial or PVC with DEHP infusion bag containing 18 mL of 0.9% Sodium Chloride Injection
- Mix gently by slowly inverting the glass vial or rocking the infusion bag. The resulting 20 mL diluted TZIELD solution contains 100 mcg/mL of TZIELD
- **If preparing a dose greater than 2000 mcg, repeat the above process with second TZIELD vial and the glass vial, or PVC with DEHP infusion bag containing 18 mL of 0.9% Sodium Chloride Injection**

TZIELD Infusion Solution Preparation

- Using an appropriately sized syringe, withdraw the volume of diluted TZIELD solution required for that day's calculated dose from the 100 mcg/mL dilution (**for a calculated dose 2000 mcg or less**) or from both prepared 100 mcg/mL dilutions (**for a calculated dose more than 2000 mcg**)
- Discard unused portion of remaining diluted TZIELD solution in the glass vial or infusion bag
- Slowly add contents of the syringe containing the TZIELD dose to PVC with DEHP infusion bag containing 25 mL of 0.9% Sodium Chloride Injection (**for a calculated dose more than 2000 mcg, add the cumulative volume for the calculated dose to a single infusion bag**). Gently rock the infusion bag to ensure that the solution mixes sufficiently. Do not shake
- Prime the PVC with DEHP IV infusion set with the TZIELD infusion solution. Do not waste any infusion solution during the priming process
- After infusion, flush the IV set with a volume of 0.9% Sodium Chloride Injection greater than or equal to the priming volume, to ensure full dose is administered. Same infusion rate should be used for flushing
- If the TZIELD infusion solution is not used immediately, store the infusion at room temperature (15°C to 30°C [59°F to 86°F]). Discard the TZIELD infusion solution if the infusion is unable to be completed within 4 hours of preparation

Use of in-line filter is not recommended. If necessary, use a polyethylene sulfone (PES) filter. Do not use light protected (colored) infusion sets.

ALT = alanine aminotransferase; AST = aspartate aminotransferase.

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

Dosing and Administration (cont'd)

Preparing Patients for Infusion With TZIELD[1]

Considerations Before Patients Start TZIELD

Laboratory and infection evaluation prior to initiation

- Prior to initiating TZIELD, obtain a complete blood count and liver enzyme tests. Use of TZIELD is not recommended in patients with
  - Lymphocyte count less than 1000 lymphocytes/mcL
  - Hemoglobin less than 10 g/dL
  - Platelet count less than 150,000 platelets/mcL
  - Absolute neutrophil count less than 1500 neutrophils/mcL
  - Elevated ALT or AST greater than 2 times the ULN or bilirubin greater than 1.5 times ULN
  - Active serious infection or chronic infection other than localized skin infections
- Prior to initiating treatment, evaluate patients for active EBV and CMV infection and confirm undetectable viral load (eg, PCR testing). Use of TZIELD is not recommended in patients with laboratory or clinical evidence of active infection with EBV or CMV (See Boxed WARNING)

Vaccinations

Administer all age-appropriate vaccinations prior to starting TZIELD

- Administer live-attenuated (live) vaccines at least 8 weeks prior to TZIELD treatment
- Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment

Considerations for Premedication and Monitoring During and After Treatment With TZIELD

Premedication

Prior to each of the first 5 days of TZIELD infusion

- Premedicate with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen
- Premedicate with an antihistamine, and
- Consider premedication with an antiemetic

If needed, administer additional premedication doses.

Recommended monitoring during and after treatment with TZIELD

- Monitor lymphocyte count regularly (every 2-3 days) during TZIELD infusion, and monitor for lymphocyte recovery following completion of TZIELD
- If prolonged severe lymphopenia (<500 cells per mcL lasting 1 week or longer) develops, permanently discontinue TZIELD
- Monitor patients for signs and symptoms of viral reactivation during TZIELD treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD
- Monitor liver enzymes and bilirubin during treatment. Discontinue TZIELD treatment in patients who develop elevated ALT or AST >5 times the ULN or bilirubin >3 times ULN
- If severe hypersensitivity reactions occur, discontinue use of TZIELD and treat promptly

Vaccinations

- Inactivated or mRNA vaccinations are not recommended within the 2 weeks prior to TZIELD treatment, during treatment, or up to 6 weeks after completion of treatment
- Live-attenuated vaccinations are not recommended within the 8 weeks prior to starting TZIELD treatment, during treatment, or up to 52 weeks after treatment

mRNA = messenger ribonucleic acid; PCR = polymerase chain reaction.

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

Ordering and Coding

Accessing TZIELD

Site of Care

TZIELD is administered by IV infusion (over a minimum of 30 minutes in adult and pediatric patients aged ≥8 years and 2 hours in pediatric patients <8 years) once daily as a single treatment course for 14 consecutive days.[1] TZIELD may be infused in a variety of outpatient settings, depending on patient and provider preference, site-of-care resources, and payer coverage. For most payers, the site(s) of care will affect the coding and billing requirements.

Site-of-care options

Hospital outpatient or infusion center (all treatment days)

Home infusion (all treatment days)

Hybrid: patient starts in infusion center, then transitions home

How to Order TZIELD

- TZIELD is available for 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 single-dose vials through Cardinal Health Specialty Distribution. If a patient will be treated at more than one site of care and you need to discuss other options, contact TZIELD COMPASS directly at 1-844-778-2246 (Monday through Friday, 8 AM–8 PM ET)

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

To establish a new account with Cardinal Health Specialty Distribution, call 866-677-4844.

Specialty pharmacies		
Amber™ Specialty Pharmacy	**P:** 888-370-1724	**F:** 877-274-4329
Chartwell Specialty Pharmacy	**P:** 800-366-6020	**F:** 412-920-1869
Orsini® Specialty Pharmacy	**P:** 800-670-5321	**F:** 877-655-4364

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We make no representation or guarantee of service or coverage of any item.

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

Ordering and Coding (cont'd)

How Supplied/Storage and Handling

How Supplied[1]

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 of TZIELD, 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 pH is 6.1.

Storage and Handling[1]

- **Refrigerate TZIELD vials** at 2°C to 8°C (36°F to 46°F)
- **Keep TZIELD vials in the original carton** to protect from light
- **Store upright**
- **DO NOT freeze or shake** the vials
- **If not used immediately, store the infusion at room temperature** (15°C to 30°C [59°F to 86°F]) and complete infusion within 4 hours of the start of preparation
- **Discard the diluted solution** if not administered within 4 hours of preparation

NDC Numbers for TZIELD[1]

NDC number*	Description of carton contents	WAC†
73650-316-01	1 TZIELD (teplizumab-mzwv) 2-mg/2-mL (1 mg/mL) single-dose vial	$14,993.15

*Some payers may require an 11-digit NDC code. In such cases, add a 0 in front of the second set of numbers, eg, 73650-316-01 would become 73650-**0316**-01.
†The list price does not reflect discounts, rebates, chargebacks, and other terms or distribution arrangements that may reduce actual sales price. Price as of January 1, 2026. Price subject to change.

NDC = National Drug Code.

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

Ordering and Coding (cont'd)

Sample Codes for TZIELD

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.** 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 solely responsible for determining the medical necessity, appropriate coding, and accuracy of claims. Sanofi does not make any representation or guarantee concerning reimbursement or coverage for any service or item.**

ICD-10-CM Diagnosis Codes[3]

A diagnosis of T1D in Stage 2 patients is required to substantiate the medical necessity of TZIELD. The following codes may be relevant when documenting a patient's Stage 2 diagnosis.

Condition	Code
Type 1 diabetes mellitus with unspecified complications	E10.8
Type 1 diabetes mellitus without complications	E10.9
Type 1 diabetes mellitus, presymptomatic, unspecified	E10.A0
Type 1 diabetes mellitus, presymptomatic, Stage 2 Confirmed islet autoimmunity with dysglycemia	E10.A2
Endocrine disorder, unspecified Endocrine disturbance NOS; hormone disturbance NOS	E34.9
Impaired fasting glucose Elevated fasting glucose	R73.01
Prediabetes Latent diabetes	R73.03

HCPCS Code for TZIELD[4]

TZIELD is billed under an HCPCS J-code.

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 micrograms.

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 = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, 10th Revision, Clinical Modification; NOS = not otherwise specified.

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

Ordering and Coding (cont'd)

Sample Codes for TZIELD (cont'd)

Administration Procedure CPT® Codes[5]

Description	Code
IV infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour	96365
+ each additional hour (list separately in addition to code for primary procedure; report 96366 for infusion intervals of greater than 30 minutes beyond 1-hour increments)	+ 96366
Chemotherapy administration, intravenous technique; up to 1 hour, single or initial substance/drug	96413*
+ each additional hour (use 96415 in conjunction with 96413; report 96415 for infusion intervals of greater than 30 minutes beyond 1-hour increments)	+ 96415
Home infusion/specialty drug administration, per visit (up to 2 hours)	99601

Home Infusion HCPCS Codes[4]

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)	S9329*
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	S9379

For additional information on coding and billing for TZIELD, scan the QR code at left or click here.

*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.

CMS = Centers for Medicare and Medicaid Services; CPT = Current Procedural Terminology.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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. Obtain a CBC prior to starting TZIELD and monitor white blood cell counts during TZIELD treatment. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), permanently discontinue TZIELD.

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

Ordering and Coding (cont'd)

Sample Codes for Testing

ICD-10-CM Codes for T1D-Related Pancreatic Islet Autoantibody Testing[3]

Description	Code
Type 1 diabetes mellitus	E10.1-E10.9
Type 1 diabetes mellitus, presymptomatic, unspecified	E10.A0
Endocrine disorder, unspecified	E34.9
Encounter for general adult medical examination without abnormal findings Encounter for adult health check-up NOS	Z00.00
Encounter for screening for diabetes mellitus	Z13.1
Family history of diabetes mellitus Conditions classifiable to E08-E13	Z83.3
Family history of other endocrine, nutritional, and metabolic diseases	Z83.49

CPT Codes for T1D-Related Pancreatic Islet Autoantibody Immunoassays[5,6]

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

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

Ordering and Coding (cont'd)

Sample Codes for Testing (cont'd)

CPT Codes for Glycemic Testing[5]

Confirm dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT); if an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate.[1]

Description	Code
Glucose tolerance test (GTT), 3 specimens (includes glucose)[7]	82951*
Glucose; quantitative, blood (except reagent strip)[7]	82947†
Glucose post glucose dose (includes glucose)[7]	82950‡
Hemoglobin glycosylated (A1C)[7]	83036

*Measured at 30-, 60-, and 90-minute time points.[7]
†Also known as fasting plasma glucose.[7]
‡Measured at 2 hours post glucose.[7]

CPT Codes Related to Monitoring

Prior to initiating TZIELD, obtain a complete blood count and liver enzyme tests. Monitor liver enzymes and white blood cell counts during treatment. Use of TZIELD is not recommended in patients with: lymphocyte count <1000 lymphocytes/mcL, hemoglobin <10 g/dL, platelet count <150,000 platelets/mcL, absolute neutrophil count <1500 neutrophils/mcL, elevated ALT or AST greater than 2 times the ULN or bilirubin greater than 1.5 times ULN, and active serious infection or chronic active infection other than localized skin infections. Discontinue TZIELD treatment in patients who develop elevated ALT or AST more than 5 times the ULN, or bilirubin more than 3 times ULN, or prolonged severe lymphopenia (<500 cells per mcL lasting 1 week or longer).[1]

Description	Code
Comprehensive metabolic panel (CMP)[5]	80053
Bilirubin, total[5]	82247§
Bilirubin, direct[5]	82248§
AST value test[5]	84450§
ALT value test[5]	84460§
Complete blood count, automated and automated differential with WBC count[5]	85025§
Complete blood count, automated[5]	85027§

§A specific test code may be required in addition to the CPT code. Please confirm which codes are required for your preferred laboratory
WBC = white blood cell..

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Ordering and Coding (cont'd)

Sample Codes for Testing (cont'd)

CPT Codes for Acute Infections

Prior to initiating treatment, evaluate patients for active EBV or CMV infection and confirm undetectable viral load. Use of TZIELD is not recommended in patients with laboratory or clinical evidence of active infection with EBV or CMV.

Condition	Code
EBV VCA IgM[8]	86665
EBV VCA IgG[8]	86665
EBV EBNA IgG[8,9]	86664
CMV IgM antibodies[5]	86645
CMV IgG antibodies[5]	86644
CMV IgG Avidity: Often reported under 86644, with additional information indicating that it is an avidity test, such as through a specific order code (eg, 006505 at Labcorp)[10]	86644
CMV DNA (quantitative PCR plasma test)[11]	87497

DNA = deoxyribonucleic acid; EBNA = Epstein-Barr virus nuclear antigen; IgG = immunoglobulin G; IgM = immunoglobulin M; VCA = viral capsid antigen.

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EHR Integration

Integrating TZIELD Into EHR Order Sets

For health systems that choose to update their electronic health record (EHR) to include TZIELD information and orders, this section outlines the information that may be considered for inclusion in order sets with TZIELD. This information is specific to TZIELD and will not work for other conditions, treatments, or therapeutic areas.

Treatment selection is always a decision made by the healthcare provider, and order sets may be overridden to reflect this. The processes outlined in this piece are variable, as not all steps apply to every customer. Any steps or settings that are not part of a customer's standard process should be excluded or modified accordingly. Any questions should be directed to the EHR vendor.

Updating order sets requires minimal time but must be implemented at the system level. It may be necessary to complete the individual components of the order set first prior to compiling them in the final order set

Suggested Content to Include in Order Sets

- Accurate diagnosis codes for TZIELD and other autoimmune disorders[3,12]
- Patient vital signs[13]
- Family history of T1D[13]
- Dosage and administration information for TZIELD[1]
- Treatment conditions, including laboratory evaluation and vaccination prior to initiation[1]
- Warnings and precautions, including viral reactivation[1]
- Patient selection criteria[1]
- Adverse reactions management[13]
- Premedications[1]
- Immunizations[1,13]

Nursing Order Sets May Also Include

- Dosing and administration guidance[1]
- Recommendations regarding missed doses[1]
- Preparation and administration instructions[1]
- IV access information[13]

For additional information on how to integrate TZIELD into EHR and workflows, scan the QR code at left or click here.

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Support and Resources

Cost and Coverage Support

Tzield® COMPASS

TZIELD COMPASS supports patients with a collaborative, comprehensive team

Field Reimbursement Managers offer providers education on

- TZIELD payer policies, coverage, and reimbursement
- Best practices for prior authorization (PA) submissions and appeals
- Product procurement options
- Considerations for navigating sites of care and scheduling infusions

Clinical Educators offer providers education and training on

- TZIELD infusion process and dosing
- Infusion coordination and scheduling
- Nursing order sets

COMPASS Navigators provide one-on-one support to patients, including

- Help navigating TZIELD product access, including the PA process and scheduling of infusions
- Education on insurance benefits, potential out-of-pocket costs, and potential financial assistance options
- Information on financial assistance options like the TZIELD Copay Program* and Patient Assistance Program

Helping patients navigate treatment cost and coverage

Copay Support

Eligible commercially insured patients may pay as little as

$0 for TZIELD

*Not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, TRICARE, or similar federal or state programs including any state pharmaceutical programs. Not valid where prohibited by law. Sanofi reserves the right to modify or terminate the Copay Program at any time without notice. Any savings provided by the Copay Program may vary depending on patients' out-of-pocket costs. Upon registration, patients receive all program details.

Eligibility requirements and terms and conditions apply. Click here for more information.

For more information on the TZIELD COMPASS program offerings, scan the QR code at left or click here.

DoD = US Department of Defense; VA = Veterans Affairs.

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Support and Resources (cont'd)

Clinical and Operational Information for TZIELD

Dosing and Administration

For additional information on the dosing, preparation, and administration of TZIELD, scan the QR code or click download below.

Download

Distribution Network

To learn more about the distribution network for TZIELD, please scan the QR code or click download below.

Download

EHR Integration

For additional information on how to integrate TZIELD into EHR and workflows, scan the QR code or click download below.

Download

Billing and Coding Guide for TZIELD

For additional information on the coding and billing of TZIELD, scan the QR code or click download below.

Download

TZIELD COMPASS

For additional information on the TZIELD COMPASS Patient Support Program, scan the QR code or click download below.

Download

Infusion Readiness Considerations

To review institutional considerations for implementing TZIELD infusion therapy, scan the QR code or click download below.

Download

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Indication and Important Safety Information

INDICATION

TZIELD (teplizumab-mzwv) is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 1 year of age and older with Stage 2 T1D.

IMPORTANT SAFETY INFORMATION

WARNING: Viral Reactivation

- **Serious, life-threatening cases of viral reactivation, including Epstein-Barr virus (EBV) and cytomegalovirus (CMV) reactivation have been reported with TZIELD. Patients who are immunocompromised are at increased risk. The majority of serious cases occurred in patients who continued TZIELD treatment despite persistent, severe lymphopenia.**
- **Test patients for active EBV and CMV infection prior to starting treatment. TZIELD is not recommended in patients with laboratory or clinical evidence of active EBV or CMV infection. Adhere to lymphocyte count monitoring requirements and discontinuation recommendations. Monitor patients for signs and symptoms of viral reactivation following TZIELD treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD.**

WARNINGS AND PRECAUTIONS

Viral Reactivation: Serious, life-threatening cases of viral reactivation, including EBV and CMV have been reported with TZIELD. During and within 2 months of TZIELD treatment, if primary infection or reactivation of EBV or CMV occurs, it may present with increased severity, including EBV-associated lymphoproliferative disease and organ failure. Patients who are immunocompromised, including patients with Down syndrome, may be at increased risk. The majority of serious viral reactivation cases occurred in patients who continued TZIELD despite persistent, severe lymphopenia. Prior to initiating treatment with TZIELD, evaluate patients for active EBV and CMV infection and confirm undetectable viral load (e.g., PCR testing). TZIELD is not recommended in patients with laboratory or clinical evidence of active EBV or CMV infection. During treatment with TZIELD, regularly monitor lymphocyte counts and monitor patients for signs and symptoms of viral reactivation during treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD and obtain viral load (e.g., PCR) promptly. If viral reactivation is confirmed, permanently discontinue TZIELD.

Cytokine Release Syndrome (CRS): CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. CRS manifestations in TZIELD-treated patients included fever, nausea (with or without vomiting), fatigue, headache, myalgia, arthralgia, increased ALT, increased AST, and increased total bilirubin. These manifestations typically occurred during the first 5 days of TZIELD treatment. 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.

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Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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. Obtain a CBC prior to starting TZIELD and monitor white blood cell counts during TZIELD treatment. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), permanently 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 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.
- Administer live vaccines at least 8 weeks prior to treatment. Live vaccines are not recommended during treatment, or up to 52 weeks after treatment.

ADVERSE REACTIONS

Most common adverse reactions were lymphopenia, vomiting, rash, leukopenia, diarrhea and headache.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm. To minimize exposure to a fetus, avoid use of TZIELD during pregnancy and at least 30 days prior to planned pregnancy. Report pregnancies to us at our Adverse Event reporting line at 1-800-633-1610 or visit https://ae.reporting.sanofi
- **Lactation:** A lactating woman may consider pumping and discarding breast milk during and for 20 days after TZIELD administration.

Please see Important Safety Information throughout and see full Prescribing Information, including Boxed Warning and patient selection criteria.

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.** CMS. 2026 ICD-10-CM tabular list of diseases and injuries. Accessed April 3, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes. **4.** CMS. HCPCS Quarterly Update: April 2026. Published March 18, 2026. Accessed April 3, 2026. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. **5.** American Medical Association. CPT® 2026 Professional Edition. American Medical Association; 2025. **6.** Simmons KM, Steck AK. American Association for Clinical Chemistry. Islet autoantibody testing. Published July 1, 2017. Accessed April 3, 2026. https://www.myadlm.org/cln/articles/2017/july/islet-autoantibody-testing-predicting-and-diagnosing-type-1-diabetes. **7.** American Diabetes Association Professional Practice Committee. Diagnosis and classification of diabetes: standards of care in diabetes—2026. *Diabetes Care*. 2026;48(suppl 1):S27-S49. **8.** Codify by AAPC. You be the coder: focus EBV lab test coding. Published January 24, 2017. Accessed April 3, 2026. https://www.aapc.com/ codes/coding-newsletters/mypathology-lab-coding-alert/you-be-the-coder-focus-ebv-lab-test-coding-153215-article. **9.** Labcorp. Epstein-Barr virus (EBV) nuclear antigen antibodies, IgG. Accessed April 3, 2026. https://www.labcorp.com/tests/010272/epstein-barr-virus-ebv-nuclear-antigenantibodies-igg. **10.** Labcorp. Cytomegalovirus (CMV) IgG avidity. Accessed April 3, 2026. https://www.labcorp.com/ tests/006505/cytomegalovirus-cmv-igg-avidity. **11.** Labcorp. Cytomegalovirus (CMV), quantitative, plasma, PCR. Accessed April 3, 2026. https://www.labcorp.com/tests/139149/cytomegaloviruscmv-quantitative-plasma-pcr. **12.** Popoviciu MS, Kaka N, Sethi Y, et al. Type 1 diabetes mellitus and autoimmune diseases: A critical review of the association and the application of personalized medicine. *J Pers Med*. 2023;13(3):422. doi:10.3390/jpm13030422. **13.** Mehta S, Ryabets-Lienhard A, Patel N, et al. Pediatric Endocrine Society Statement on Considerations for Use of Teplizumab (Tzield™) in Clinical Practice. *Horm Res Paediatr*. Published online April 30, 2024. doi:10.1159/000538775.

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