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

Prior Authorization Checklist

For Appropriate Patients Recently Diagnosed With Stage 3 T1D

Your practice may need to obtain prior authorization (PA) from a health plan before it will cover TZIELD

This checklist is for informational purposes only and does not constitute medical, legal, or reimbursement advice. This document represents no statement, promise, or guarantee of coverage or payment. Always check with the patient's insurance regarding specific requirements when submitting a PA. Individual health insurance policies are frequently updated, and it is the responsibility of the provider and their office staff to determine appropriate coding, medical necessity, site of service, and documentation requirements, and to submit appropriate codes and charges for services rendered, as specified by the patient's health insurance.

The information in this checklist is general and is not intended to be conclusive or exhaustive. As the patient's healthcare provider, you are responsible for applying your clinical judgment regarding appropriate care and treatment of each patient.

INDICATIONS

TZIELD (teplizumab-mzwv) is indicated to:

- Delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric patients 1 year of age and older with Stage 2 T1D.
- Delay the decline in endogenous insulin production in pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 T1D. This indication is approved under accelerated approval based on evidence of reduced C-peptide decline. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Limitations of Use:

- There is limited evidence of safety and effectiveness in patients aged 45 years and older with Stage 2 T1D.
- TZIELD is not effective as a disease modifying therapy in non-autoimmune dysglycemic conditions.

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. Serious cases have also been reported in adults with higher body surface area or comorbid conditions, such as adrenal insufficiency or cardiovascular disease. The majority of serious cases occurred in patients who continued TZIELD treatment despite persistent, severe lymphopenia. Severe lymphopenia may be prolonged in adults.**
- **Test patients for active EBV and CMV infection prior to starting treatment. TZIELD is contraindicated in patients who are immunocompromised or have active viral infection (such as 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 additional Important Safety Information on the next page and full Prescribing Information, including Boxed WARNING and patient selection criteria.

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Common Health Plan PA Requirements

PA Criteria	Supporting Documentation and Sample Codes
✓ **General patient information** • Patient name • Date of birth • Member ID • Medical records and chart notes • Details on why the treatment is medically necessary	Additional patient information may be required, depending on your patient's insurance provider. Be sure to check with the patient's insurance and coverage policy regarding specific requirements.
✓ **Patients 8 to 17 years of age**[1]	TZIELD is not indicated for recently diagnosed Stage 3 patients under 8 years of age or over 17 years of age.[1]
✓ **Confirmation of recent diagnosis within 8 weeks of Stage 3 T1D**[1] • Attach all lab reports that support the patient's diagnosis, ensuring that the testing date is visible • Include the appropriate ICD-10-CM codes to support the patient's diagnosis	**Diagnosis code descriptions**[2] / **ICD-10-CM Code** Type 1 diabetes mellitus: E10 Type 1 diabetes mellitus with ketoacidosis: E10.1 Type 1 diabetes mellitus with ketoacidosis without coma: E10.10 Type 1 diabetes mellitus with ketoacidosis with coma: E10.11 Type 1 diabetes mellitus with other specified complications: E10.6 Type 1 diabetes mellitus with hyperglycemia: E10.65 Type 1 diabetes mellitus with unspecified complications: E10.8 Type 1 diabetes mellitus without complications: E10.9
• **Positive for at least 1 pancreatic islet cell autoantibody**[1] – Provide documentation of recent lab reports. Some health plans may require lab reports from tests conducted within a specified period of time	**Provide recent documentation of at least 1**[1,3]**:** / **CPT® Code** Glutamic acid decarboxylase 65 (GAD) autoantibody: 86341 Insulinoma-associated antigen 2 autoantibody (IA-2A): 86341 Zinc transporter 8 autoantibody (ZnT8A): 86341 Islet cell antibody (ICA): 86341 Insulin autoantibody (IAA): 86337
• **Peak C-peptide ≥0.2 pmol/mL on a mixed-meal tolerance test**[1] – If a mixed meal tolerance test is not available, an alternative method for measuring peak C-peptide ≥0.2 pmol/mL may be appropriate	**Results of C-peptide testing confirm peak of ≥0.2 pmol/mL**[1,3] / **CPT® Code** C-peptide: 84681*,† Glucose; quantitative, blood (except reagent strip): 82947* Collection of venous blood by venipuncture: 36415‡
✓ **Ensure that the clinical history of the patient does not suggest type 2 diabetes**[1]	TZIELD is not effective as a disease modifying therapy in non-autoimmune dysglycemic conditions.[1]
✓ **Confirm that all documentation requirements have been met per payer policy**	Submit medical records, labs required prior to initiation, and chart notes providing evidence for all the required policy criteria.

CPT = Current Procedural Terminology; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.

*Measured at various time points.
†If drawing a mixed-meal tolerance test, codes 82951 and 82952 may be appropriate.
‡Do not report modifier 63 in conjunction with 36415.[3]

TZIELD COMPASS can offer assistance to help navigate the steps throughout the payer coverage and reimbursement process. Call 1-844-778-2246 Monday through Friday, 8 AM to 8 PM ET.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

TZIELD is contraindicated in patients who are immunocompromised or have active viral infection (such as EBV or CMV infection).

WARNINGS AND PRECAUTIONS

Viral Reactivation: Serious, life-threatening cases of viral reactivation, including EBV and CMV infections 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. The duration of severe lymphopenia following TZIELD treatment may be prolonged in adults. Serious cases have also been reported in adults with higher body surface area or comorbid conditions, such as adrenal insufficiency or cardiovascular disease.

Prior to initiating treatment with TZIELD, evaluate patients for active EBV and CMV infection and confirm absence of active infection on assessment of viral load (e.g., PCR testing). 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.

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

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. Manifestation of CRS 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 if symptoms have resolved or significantly improved, subsequently administering the remaining doses on consecutive days to complete the full 14-day treatment course in patients with Stage 2 T1D or each of the two 12-day courses in patients with Stage 3 T1D; **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: Bacterial and viral infections have occurred in TZIELD-treated patients. Adults may have a longer duration of severe lymphopenia following TZIELD treatment, which may increase the risk of 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. Severe lymphopenia (<500 cells per mcL) lasting 1 week or longer has been reported in TZIELD-treated patients.

Severe lymphopenia following TZIELD treatment may be more prolonged in adults. Obtain a CBC prior to starting TZIELD and monitor lymphocyte 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.

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

ADVERSE REACTIONS

Most common adverse reactions were lymphopenia, vomiting, rash, leukopenia, diarrhea, neutropenia, increased liver transaminase 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 full Prescribing Information, including Boxed WARNING and patient selection criteria.

References: 1. TZIELD Prescribing Information. Provention Bio, Inc. **2.** CMS. 2026 ICD-10-CM tabular list of diseases and injuries. Accessed June 12, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes. **3.** American Medical Association. CPT® 2026 Professional Edition. American Medical Association; 2025.

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