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

PRIOR AUTHORIZATION CHECKLIST

Your practice may need to obtain prior authorization (PA) from a health plan before it will cover TZIELD® (teplizumab-mzwv). This checklist may be used to organize and record patient information that may be needed when completing a PA form.

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.

Please see additional Important Safety Information on page 3 and full Prescribing Information, including Patient Selection Criteria, and Medication Guide.

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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.

PA CRITERIA TO CONSIDER

Many policies require you to provide the following information in a PA:

PA Criteria	Supporting Documentation
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.
Patient is aged 8 years and older[1]	TZIELD is not indicated for patients under 8 years of age.[1]
Confirm diagnosis of Stage 2 type 1 diabetes (T1D)[1-3] • Include the appropriate ICD-10-CM codes to support the patient's diagnosis • Confirm that the patient's clinical history and associated diagnosis codes **do not** suggest Stage 3 T1D (clinical symptoms and overt hyperglycemia), or type 2 diabetes	**Sample diagnosis codes**[3] ICD-10 Code: E10.8 — Type 1 diabetes mellitus with unspecified complications ICD-10 Code: E10.9 — Type 1 diabetes mellitus without complications **Note:** There are currently no diagnosis codes specific to Stage 2 T1D; as the presence of ≥2 pancreatic islet autoantibodies is consistent with a diagnosis of T1D, the diagnosis codes listed above may be applicable.[2]
Positive for at least 2 pancreatic islet cell autoantibodies[1] • Provide documentation of recent lab reports. Some health plans may require lab reports from tests conducted within the previous 6 months • Commercial lab assays performed under CPT codes 86341 and/or 86337 are recommended[5]	**Provide recent documentation of at least 2 of the following**[1]: • Glutamic acid decarboxylase 65 (GAD) autoantibodies • Insulin autoantibodies (IAA) • Insulinoma-associated antigen 2 autoantibodies (IA-2A) • Zinc transporter 8 autoantibodies (ZnT8A) • Islet-cell autoantibodies (ICA)
Dysglycemia (abnormal blood glucose) without overt hyperglycemia using an oral glucose tolerance test (OGTT)[1] • Provide documentation from results of an OGTT. Some health plans may require an OGTT be conducted within the previous 2 months • Confirm that the patient's clinical history and associated diagnosis codes **do not** suggest overt hyperglycemia (FPG ≥126 mg/dL or 2-h PG ≥200 mg/dL during OGTT)[2] **OR** if an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate[1]	**Results of OGTT indicate dysglycemia defined by one of the following**[2,4]: • Fasting plasma glucose (FPG) 100-125 mg/dL *or* • 2-hour plasma glucose (2-h PG) 140-199 mg/dL *or* • 30-, 60-, or 90-minute plasma glucose value on OGTT ≥200 mg/dL **Note:** Some health plans may require FPG levels of **110**-125 mg/dL, as these values were utilized for the inclusion criteria of the pivotal study for TZIELD.[4] Always check the patient's insurance and coverage policy regarding specific requirements. **Note:** While the TZIELD Prescribing Information and ADA guidelines allow for alternative measurements of dysglycemia, health plan policies may require an OGTT, as it was utilized and required for the inclusion criteria of the pivotal study for TZIELD.[4] Always check the patient's insurance and coverage policy regarding specific requirements.
Ensure that the clinical history of the patient does not suggest type 2 diabetes[1]	TZIELD is not indicated for patients with type 2 diabetes.[1]
If applicable, provide attestation that the patient has a biological relative with T1D	**Note:** Health plan policies may require attestation that a patient has a biological relative diagnosed with T1D, as it was required per the inclusion criteria of the pivotal study for TZIELD.[4] Always check the patient's insurance and coverage policy regarding specific requirements.
Confirm that all documentation requirements have been met	Submit medical records, lab reports, and chart notes providing evidence for all the required policy criteria.

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

ADA = American Diabetes Association; CPT = Current Procedural Terminology; ICD-10 = International Classification of Diseases, Tenth Revision.

Provention Bio 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.

Please see Important Safety Information on pages 1 and 3 and full Prescribing Information, including Patient Selection Criteria, and Medication Guide.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

- **Serious Infections:** Use of TZIELD is not recommended in patients with active serious infection or chronic infection other than localized skin infections. Monitor patients for signs and symptoms of infection during and after TZIELD administration. If serious infection develops, treat appropriately, and discontinue TZIELD.
- **Lymphopenia:** Lymphopenia occurred in most TZIELD-treated patients. For most patients, lymphocyte levels began to recover after the fifth day of treatment and returned to pretreatment values within two weeks after treatment completion and without dose interruption. Monitor white blood cell counts during the treatment period. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), discontinue TZIELD.
- **Hypersensitivity Reactions:** Acute hypersensitivity reactions including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in TZIELD-treated patients. If severe hypersensitivity reactions occur, discontinue TZIELD and treat promptly.
- **Vaccinations:** The safety of immunization with live-attenuated (live) vaccines with TZIELD-treated patients has not been studied. TZIELD may interfere with immune response to vaccination and decrease vaccine efficacy. Administer all age-appropriate vaccinations prior to starting TZIELD.
  - Administer live vaccines at least 8 weeks prior to treatment. Live vaccines are not recommended during treatment, or up to 52 weeks after treatment.
  - Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment. Inactivated vaccines are not recommended during treatment or 6 weeks after completion of treatment.

ADVERSE REACTIONS: Most common adverse reactions (>10%) were lymphopenia, rash, leukopenia, and headache.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm.
- **Lactation:** A lactating woman may consider pumping and discarding breast milk during and for 20 days after TZIELD administration.

Please see additional Important Safety Information on page 1 and full Prescribing Information, including Patient Selection Criteria, and Medication Guide.

References: 1. TZIELD. Prescribing Information. Provention Bio, Inc. **2.** American Diabetes Association Professional Practice Committee. 2. Classification and diagnosis of diabetes: standards of medical care in diabetes—2023. *Diabetes Care*. 2023;46(suppl 1):S19-S40. **3.** ICD10data.com. Type 1 diabetes mellitus E10. Accessed April 14, 2023. https://www.icd10data.com/ICD10CM/Codes/E00-E89/E08-E13/E10-. **4.** National Institutes of Health. Anti-CD3 mAb (teplizumab) for prevention of diabetes in relatives at-risk for type 1 diabetes mellitus. Trial protocol TN-10. June 25, 2014. Accessed May 9, 2023. https://repository.niddk.nih.gov/media/studies/tn10-anti-cd3-prevention/Protocol.pdf. **5.** American Medical Association. *CPT® 2021 Professional Edition*. American Medical Association; 2021.

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