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

Tzield® COMPASS

For TZIELD® (teplizumab-mzwv) Injection 2 mg/2 mL

Patient Treatment Pathway

What Is TZIELD?

TZIELD is a disease-modifying treatment for type 1 diabetes (T1D).[1-3] It is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with Stage 2 T1D.[4]

How Is TZIELD Administered?

TZIELD is administered by intravenous (IV) infusion over a minimum of 30 minutes, once daily for 14 consecutive days using body surface area–based dosing.[4] You should plan for additional time before and after infusion for preparation and monitoring.

Beginning Treatment

You and your patient have decided that TZIELD is right for them. This resource outlines each of the key milestones and steps both you and your patient will take along the treatment path. COMPASS Navigators, Therapeutic Education Managers (TEMs), and Field Reimbursement Managers (FRMs) are ready to assist you and your patients every step of the way (see page 10 or click "TZIELD COMPASS" tab below for more information).

All TZIELD COMPASS personnel are provided through Sanofi and do not work under the direction of the healthcare provider (HCP) or give medical advice. They are trained to direct patients to their HCPs for treatment-related questions and advice.

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 Important Safety Information on pages 1, 2, and 11 and full Prescribing Information, including Patient Selection Criteria, by clicking on the tabs below.

Identifying Appropriate Patients

TZIELD is indicated to delay the onset of Stage 3 T1D in adults and pediatric patients 8 years of age and older with Stage 2 T1D.[4]

The following labs should be completed prior to prescribing TZIELD and enrolling your patient in TZIELD COMPASS in order to determine clinical eligibility and meet coverage requirements.

- **Patient has tested positive for at least 2 of the following pancreatic islet cell autoantibodies within the past 6 months[4,*]**
  - Glutamic acid decarboxylase 65 autoantibody (GADA)
  - Insulin autoantibody (IAA)
  - Insulinoma-associated antigen 2 autoantibody (IA-2A)
  - Zinc transporter 8 autoantibody (ZnT8A)
  - Islet cell autoantibody (ICA)

- **Patient has been diagnosed with dysglycemia without overt hyperglycemia, such as[4,5,*,†]**
  - Fasting plasma glucose (FPG) of 100–125 mg/dL
  - 2-hour plasma glucose (2-h PG) during an oral glucose tolerance test (OGTT) of 140–199 mg/dL
  - Intervening plasma glucose level at 30, 60, or 90 minutes of ≥200 mg/dL during an OGTT
  - A1C of 5.7%–6.4% or ≥10% increase in A1C

- **Ensure the clinical history of the patient does not suggest type 2 diabetes[4]**

To prevent delays in support, please be sure that all fields have been completed, clinical labs are attached, and patient consent is signed

*Timelines for lab requirements may vary by individual plan.

†If an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate.

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.

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After a provider has determined that TZIELD is appropriate for their patient, the path to treatment begins

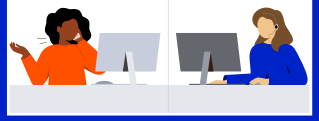
Prescribing TZIELD and Insurance Approval

Step 1

Consider SOC and Infusion Method

Confirm patient meets pre-infusion requirements and work with patient/caregiver to determine where and how to infuse TZIELD.

Step 2



Enroll in TZIELD COMPASS

Enroll a patient in TZIELD COMPASS to access the resources and support available through the program.

Step 3

Finalize Insurance Coverage

Work with TZIELD COMPASS, which can help finalize insurance coverage for TZIELD.

TZIELD Treatment and Follow-Up

Step 4

Schedule Infusion

Schedule the patient and order labs as required.

Step 5

Complete Infusion

Confirm product and premedication delivery and monitor patient throughout treatment.

Step 6

Post-infusion Follow-Up

Create post-infusion monitoring plan and handle reimbursement.

Patient expectations along treatment pathway

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Patient learns about SOC options and infusion methods.	Patient consents to TZIELD COMPASS enrollment and is educated on support offerings.	Patient makes final decision on SOC and infusion method.	Patient is scheduled for 14-day infusion.[4]	Patient is infused and has check-ins during the 14-day treatment.[4]	Patient discusses post-infusion monitoring and is reminded of continued support from TZIELD COMPASS.

SOC = site of care.

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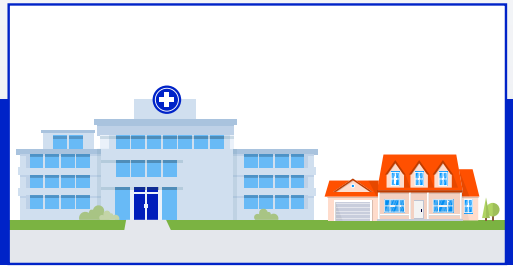

Consider SOC and Infusion Method

To understand your patient's preferences and not delay insurance approval, be sure to do the following:

- Identify the patient's potential infusion location(s) (eg, office, home, or both) based on their insurance coverage, location, transportation, and scheduling needs
- Determine the patient's method of infusion, via daily IV, midline, or peripherally inserted central catheter (PICC), as well as required labs
- Provide this information to TZIELD COMPASS to obtain assistance with the insurance coverage review process

Important notes for your patients:

Help them understand their SOC choices and the different treatment and logistical considerations involved with each option

—

Explain the differences between infusing using an IV, midline, or PICC and which choice may be best for them

—

Ensure they understand that their choices depend on their insurance coverage and that the TZIELD COMPASS team will help obtain approval

COMPASS Navigators can assist with benefits verification and FRMs can help your office navigate SOC options

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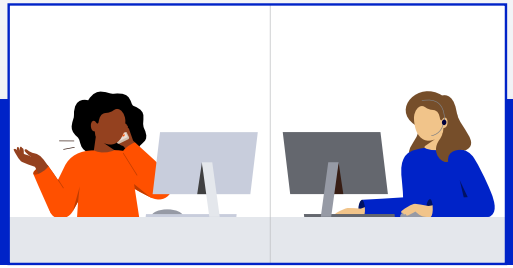

Enroll in TZIELD COMPASS

To activate and get the most out of your TZIELD COMPASS support team, be sure to do the following:

- Provide information to your patient on the TZIELD COMPASS patient support program and how it can help with insurance coverage and education
- Complete the healthcare provider (HCP) portion of TZIELD COMPASS enrollment and ensure there is no missing information
- Utilize TZIELD COMPASS, which can help you connect with a TEM for any questions you or your patient may have on what to expect during infusion
- Inform patient a TEM can help connect them to a TZIELD Mentor, a real patient or caregiver who has experienced TZIELD treatment firsthand

Important notes for your patients:

Let them know a dedicated COMPASS Navigator will reach out to welcome them and be their point of contact throughout the entire treatment process

—

Ensure patient or authorized caregiver provides enrollment consent via a signature or eConsent, and confirm their contact and insurance information

—

Help them connect with a TEM and TZIELD Mentor, as they can provide support and answer questions patients may have

FRMs can provide education and support on enrollment form submissions, while TEMs can provide education on the infusion process

Please see Important Safety Information on pages 1, 2, and 11 and full Prescribing Information, including Patient Selection Criteria, by clicking on the tabs below.

Finalize Insurance Coverage

To gain insurance approval so treatment with TZIELD can begin, be sure to do the following:

- Work with TZIELD COMPASS to understand insurance coverage requirements and navigate completion of prior authorizations
- Complete a letter of medical necessity and/or address insurance concerns via the appeals process, as needed, to help ensure coverage approval
- Help patient make final selections regarding their preferred SOC options and infusion method based on their insurance coverage

Important notes for your patients:

Along with a COMPASS Navigator, help them understand their insurance coverage and finalize their treatment decisions

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Review financial assistance options, including the TZIELD Copay Program, that may be available to them based on their coverage

—

Help them complete any final paperwork needed so treatment can begin

FRMs can provide in-office support to help educate on plan requirements and navigating the PA and appeals process

Please see Important Safety Information on pages 1, 2, and 11 and full Prescribing Information, including Patient Selection Criteria, by clicking on the tabs below.

Schedule the Infusion

To get the patient scheduled so they can begin receiving treatment, be sure to do the following:

- Work with your patient to schedule their 14-day course of therapy[4]
- Order baseline labs in accordance with label[4] and payer policy, including complete blood count (CBC) with differential and liver enzyme tests*
- Administer all age-appropriate vaccinations prior to starting TZIELD†
- Premedicate prior to TZIELD infusion for the first 5 days of dosing with an NSAID or acetaminophen, an antihistamine, and/or an antiemetic. Administer additional doses of premedication if needed[4]

Important notes for your patients:

Coordinate with them to schedule their first appointment, ensuring they are available over a continuous, 14-day period[4]

—

Work with them to review pre-infusion medication instructions and to complete any pre-infusion lab work and vaccinations

—

Answer any remaining questions they may have as they prepare to begin their infusions

COMPASS Navigators will coordinate and confirm infusion appointments

*Run CBC and liver enzyme tests to confirm patient has adequate hematologic function, adequate hepatic function, does not have evidence of acute infection with Epstein-Barr virus or cytomegalovirus, and does not have an active serious infection or chronic active infection other than localized skin infections.[4]

†Administer live-attenuated (live) vaccines at least 8 weeks prior to treatment. Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment.[4]

mRNA = messenger ribonucleic acid; NSAID = nonsteroidal anti-inflammatory drug.

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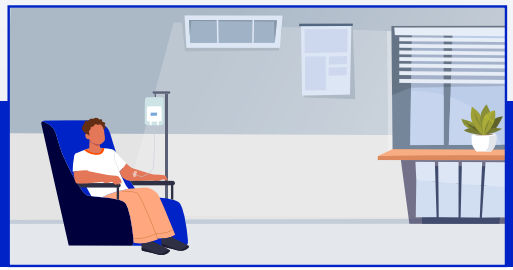

Complete the 14-Day Infusion

To help ensure the patient successfully completes their treatment cycle, be sure to do the following:

- Check for notification from COMPASS Navigator or FRM that TZIELD has shipped
- Perform check-ins to answer questions, discuss side effects, and help prepare patients to stay on track during treatment
- Confirm successful completion of infusion courses on Day 14[4]
- Collaborate with TEM regarding nursing orders, such as contact information for check-ins, premedication needs, and required labs

Important notes for your patients:

Help them confirm that the infusion site or home infusion providers are ready to help ensure a successful start to treatment

—

Be sure to check in with them regularly to monitor progress and answer any questions that may arise

—

Remind them that a COMPASS Navigator will be checking in with them throughout the course of their treatment

COMPASS Navigators will check in throughout the infusion process to answer any questions you may have

Please see Important Safety Information on pages 1, 2, and 11 and full Prescribing Information, including Patient Selection Criteria, by clicking on the tabs below.

Post-infusion Follow-Up

To ensure appropriate post-treatment monitoring and follow-up care, be sure to do the following:

- Discuss your plan for post-infusion monitoring and follow-up now that TZIELD infusions are complete
- Remind patients that TZIELD COMPASS is available even after they have completed therapy to address copay/insurance questions

Important notes for your patients:

Review their post-infusion plan so they understand what to expect now that treatment is complete

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Remind them that their COMPASS Navigator is still available to help address any post-treatment and insurance questions that may arise

COMPASS Navigators and FRMs can help with billing questions

Please see Important Safety Information on pages 1, 2, and 11 and full Prescribing Information, including Patient Selection Criteria, by clicking on the tabs below.

TZIELD COMPASS

TZIELD COMPASS is a support program that is designed to provide helpful tools and resources, information on reimbursement and financial assistance options, and additional support related to the treatment pathway.

Call TZIELD COMPASS at **1-844-778-2246**
Monday to Friday, 8 AM–8 PM ET

Visit **www.tzieldhcp.com/tzield-compass** to learn more

TZIELD COMPASS is a patient support program that helps eligible patients gain access to TZIELD and provides them with education and resources related to TZIELD.

TZIELD support teams can help with the following:

COMPASS Navigator

- Verification of health plan coverage
- Benefits investigation and PA support
- Patient Assistance Program education
- Coordination between HCP, patient, and specialty pharmacy
- Copay assistance education*
- Site of care options and logistical information
- Infusion check-ins and post-infusion feedback gathering

TEM

- Patient and caregiver education on the TZIELD infusion process
- Support for HCP teams with information on infusion-related questions
- Infusion education and training for infusion sites, pharmacy staff, and home health nurses
- Ensure sites, including institutions, are infusion-ready and well versed in product procurement and reimbursement

FRM

- Education on the TZIELD COMPASS enrollment form and supporting documentation
- Education on payer policies, PA requirements, and navigating the denial/appeal process
- Billing and coding education for both existing and prospective SOCs

*This program is intended to help with the cost of TZIELD and its infusion administration only. It does not help with the cost of other medicines you take at the same time as TZIELD or with other facility fees. Not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs including any state pharmaceutical assistance programs. Not valid where prohibited by law. Savings may vary depending on patients' out-of-pocket costs. Sanofi reserves the right to modify or terminate the program at any time without notice.

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

Please see Important Safety Information on pages 1, 2, and 11 and full Prescribing Information, including Patient Selection Criteria, by clicking on the tabs below.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

- **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 full Prescribing Information, including Patient Selection Criteria, by clicking on the tabs below.

References: 1. Herold KC, Gitelman SE, Gottlieb PA, Knecht LA, Raymond R, Ramos EL. Teplizumab: a disease-modifying therapy for T1D that preserves ß-cell function. *Diabetes Care*. 2023;46(10):1848-1856. **2.** FDA approves Tzield™—a watershed moment for T1D community. Published November 17, 2022. Accessed March 4, 2025. https://www.jdrf.org/blog/2022/11/17/fda-approves-tzield-teplizumab-watershedmoment-t1dcommunity/#:~:text=FDA. **3.** U.S. Food and Drug Administration. FDA approves first drug that can delay onset of T1D. PR Newswire. November 17, 2022. Accessed March 6, 2025. https://www.prnewswire.com/news-releases/fda-approves-first-drug-that-can-delay-onset-of-type-1-diabetes-301682219.html. **4.** TZIELD. Prescribing information. Provention Bio, Inc. **5.** American Diabetes Association Professional Practice Committee. 2. Diagnosis and classification of diabetes: standards of medical care in diabetes—2025. *Diabetes Care*. 2025;48(suppl 1):S27-S49.

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