

TziELD[®]
(teplizumab-mzwv)
Injection | 2mg/2mL



Pediatric vaccination considerations

Important information to help navigate immunization schedules around TZIELD

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

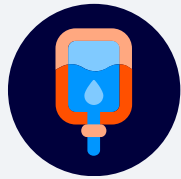
WARNING: Viral Reactivation

- **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 full [Prescribing Information](#), including **Boxed WARNING** and patient selection criteria.

Considerations for vaccination¹

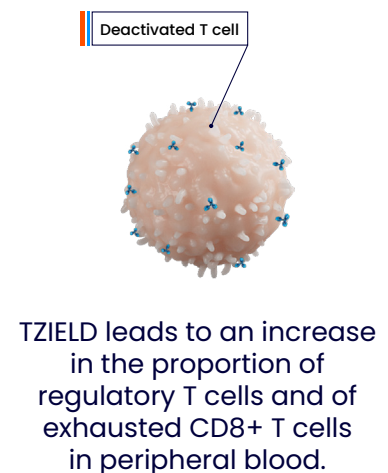
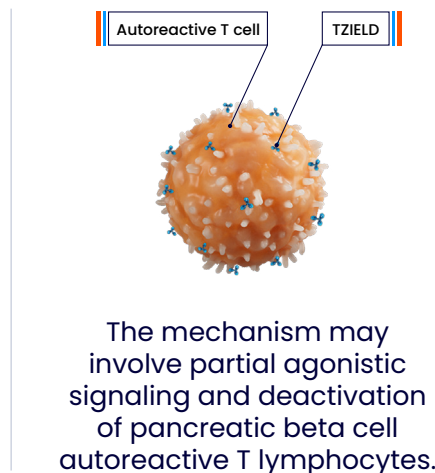
Recommended dosing schedule for patients with Stage 2 T1D



TZIELD is a single-course treatment administered by intravenous infusion over 14 consecutive days

- Do NOT administer 2 doses on the same day
- If an infusion is missed, resume by administering all remaining doses on consecutive days to complete the 14-day course

TZIELD Mechanism of Action



IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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TZIELD and immunization schedules¹

TZIELD may interfere with the immune response to vaccination and decrease vaccine efficacy. Administer all age-appropriate vaccinations prior to starting TZIELD.



The safety of immunization with live-attenuated vaccines in TZIELD-treated patients has not been studied¹

Inactivated or mRNA vaccines¹



- Administer inactivated (killed) vaccines or mRNA vaccines **at least 2 weeks prior to treatment**
- 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 vaccines¹



- Administer live-attenuated (live) vaccines **at least 8 weeks prior to 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



Before starting TZIELD in your appropriate patients, please consult the AAP recommended vaccination schedule for those 18 years and younger

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AAP= American Academy of Pediatrics.

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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Set your patients up appropriately¹



Administer
all age-appropriate vaccinations

Refer to this guide to help ensure your patients can receive their appropriate vaccines during their appropriate window.



Visit TZIELDhcp.com to learn more about TZIELD for patients 1 year and older with Stage 2 T1D

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 mL 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.

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Reference: 1. TZIELD Prescribing Information. Provention Bio, Inc.

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