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

CONSIDERATIONS FOR TZIELD INFUSIONS AT HOME

If you prescribed your patients TZIELD to be administered at home, the specialty pharmacy will require additional information for the infusion process. When placing a supply order for TZIELD, consider including the below information in addition to any specific supplies that will be needed.

The following information is provided for informational purposes only and is not intended to provide medical advice. An order for home healthcare is at the discretion of the provider, who should exercise independent clinical judgment for such orders for each individual patient.

PATIENT INFORMATION

Provide information on the patient who will receive the infusion and guardian/caregiver information if applicable.

PRESCRIBER INFORMATION

Include information about you and your practice.

PREMEDICATION FOR TZIELD INFUSIONS

Specify which premedications you will be prescribing during treatment with TZIELD.

As stated in the Prescribing Information, premedicate prior to TZIELD infusions for the first 5 days of dosing with: a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic.

TZIELD TREATMENT REGIMEN

The recommended TZIELD dosage for adults and pediatric patients aged 8 years and older uses body surface area (BSA)-based dosing. Confirm the patient's height, weight, body surface area, dosing regimen, and the date these measurements were obtained.

CALCULATION

How to calculate BSA using the Mosteller formula:

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

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

When calculating BSA, round to the nearest 100th using standard rounding rules (example: 0.93 m^2).

INDICATION

TZIELD 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 the following page and full Prescribing Information, including Medication Guide.

The patient's BSA can be used to calculate the recommended dosage for each of the 14 days:

Day 1	Day 2	Day 3	Day 4	Days 5-14
65 mcg/m²	125 mcg/m²	250 mcg/m²	500 mcg/m²	1030 mcg/m²

SKILLED NURSING VISIT & ORDERING SUPPLIES

Provide detailed instructions for skilled nursing visit, infusion, and clinical monitoring. Indicate if you will be ordering any additional supplies, such as an infusion pump, IV pole, back-up peripheral IV kit, and any other supplies you determine necessary.

For more information on dosing and administration, please refer to the **Prescribing Information** for TZIELD.

TZIELD INFUSION REACTION MANAGEMENT ORDERS

Include any necessary medications and instructions for your desired standard of care in case of an infusion reaction.

MONITORING DIRECTIONS

Provide directions for monitoring patients during and after infusion.

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. 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 and Medication Guide.

FOR QUESTIONS OR ADDITIONAL INFORMATION, CONTACT THE APPROPRIATE SPECIALTY PHARMACY

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

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