



Actor portrayal

Talking to your doctor about **TZIELD**[®] (teplizumab-mzww)

For the first time ever, it may be possible to delay the onset of type 1 diabetes (Stage 3 T1D)—with TZIELD. In this guide, you'll find helpful information about treatment and some questions to help you prepare for a conversation with your doctor.

WHAT IS TZIELD?

TZIELD is a prescription medicine used to delay the onset of Stage 3 type 1 diabetes, which is when your body can't make enough insulin on its own and may require insulin injections. TZIELD is for **adults and children 8 years of age and older who have Stage 2 type 1 diabetes**. This means they have tested positive for 2 or more type 1 diabetes-related autoantibodies, have abnormal blood sugar levels, and do not have type 2 diabetes. It is not known if TZIELD is safe and effective in children under 8 years of age.

HOW DOES T1D *occur in the body?*

T1D is an autoimmune disease. It occurs when the **immune system attacks the cells in the pancreas that make insulin**, called beta cells. But T1D happens in stages. The attack on the beta cells starts before you need insulin injections. This is called early-stage T1D. During this stage, two or more T1D autoantibodies are present in the blood.

1

What are the stages of T1D?

2

How could I/my child prepare for Stage 3 T1D?

3

What are some of the challenges of living with Stage 3 T1D?

HOW DO I KNOW IF TZIELD *could be right for me or my child?*

TZIELD is for **people age 8 years and older who have Stage 2 T1D**. Stage 2 means they have early-stage T1D and abnormal blood sugar levels. A blood test can detect early-stage T1D by looking for 2 or more T1D autoantibodies.

1

How can I/my child get screened for early-stage T1D?

2

How do I test my/my child's blood sugar levels?

3

What do the test results mean for me/my child?

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TZIELD?

TZIELD may cause serious side effects, including:

- **Cytokine Release Syndrome (CRS)**. Signs and symptoms of CRS problems may include:
 - » fever
 - » feeling tired (fatigue)
 - » muscle and joint pain
 - » nausea
 - » headache
 - » increased liver enzymes in your blood

These signs and symptoms may start during the first 5 days of TZIELD treatment. Tell your healthcare provider right away if you develop any signs and symptoms of CRS during treatment with TZIELD.

Please see **Important Safety Information** throughout.
Please see **Medication Guide** and **Prescribing Information**.



Continuing the conversation WITH YOUR DOCTOR

HOW DOES TZIELD *work?*

TZIELD attaches to certain cells in the immune system and delays the onset of Stage 3 T1D. It may work **by turning off the immune system cells that attack beta cells**, which produce insulin and are found in the pancreas.

1

How is TZIELD thought to slow down the immune system's attack?

2

Does TZIELD change my/my child's immune system or body in any other ways?

HOW COULD TZIELD *help?*

A clinical trial showed that with TZIELD, **people had 2 more years before the onset of Stage 3 T1D**, compared with placebo.

The median* time to diagnosis was 50 months for those who were given TZIELD, compared with 25 months for those who were given placebo.

The most common side effects for people who were given TZIELD were **rash (36% of people), decrease in white blood cell counts (leukopenia, 21% of people), and headache (11% of people)**.

The clinical trial that explored the safety and effectiveness of TZIELD for delaying the onset of Stage 3 T1D included 76 people. The participants had Stage 2 T1D. 44 people in this trial were given TZIELD. 32 people in the trial were given placebo. People in the trial were followed until they were diagnosed with Stage 3 T1D. The median* follow-up time was 51 months (just over 4 years). People not diagnosed with Stage 3 T1D were followed for different periods of time. Your results may vary.

1

What are some of the other results from the clinical trial?

2

What should I know about the side effects of TZIELD?

*Median is the middle number in a group of numbers arranged from lowest to highest.

IMPORTANT SAFETY INFORMATION (CONT'D)

What is the most important information I should know about TZIELD?

TZIELD may cause serious side effects, including:

- **Decrease in white blood cells.** TZIELD may cause a decrease in a type of white blood cell called lymphocytes. A decrease in white blood cells is a serious, but common side effect that can affect your body's ability to fight infections.

Your healthcare provider will do blood tests to check your liver and your complete blood counts before you start treatment and during treatment with TZIELD. During and after your treatment with TZIELD, your healthcare provider will check for serious side effects, as well as other side effects, and treat you as needed. Your healthcare provider may temporarily or completely stop your treatment with TZIELD, if you develop liver problems, have a serious infection, or if your blood counts stay too low.

Please see **Important Safety Information** throughout.
Please see **Medication Guide** and **Prescribing Information**.



Continuing the conversation WITH YOUR DOCTOR

HOW IS TZIELD *given?*

TZIELD is an intravenous (IV) infusion. This means it's **given through a needle into a vein in your arm**. Infusions are given once a day, every day for 14 days in a row. Each infusion is at least 30 minutes long. You will also need some extra time before and after each infusion. This is so a nurse can prepare the infusion and monitor you or your child for a short period afterwards.

If you miss a scheduled infusion, your doctor will continue your treatment on the next scheduled day. You will not receive 2 infusions on the same day.

1

Where would the infusions take place?

2

What should I expect after getting the infusions?

3

How can I schedule the infusions?

GUIDING YOU THROUGH THE TREATMENT EXPERIENCE



Provention Bio COMPASS was created with one goal in mind: to guide you through the treatment process from start to finish and help make the experience as smooth as possible.

Learn more about the program by visiting TZIELD.com/COMPASS

Provention Bio COMPASS is a patient support program that helps patients to gain access to TZIELD and provides patients with education and resources related to TZIELD. Provention Bio COMPASS is not a healthcare service or an insurance provider and does not provide care coordination. Be sure to always contact your physician if you have any questions about your health or treatment with TZIELD. Provention Bio COMPASS and your COMPASS Navigator will not provide medical or treatment advice. Provention Bio COMPASS services are available only to those who have been prescribed TZIELD and are intended for US residents only.

IMPORTANT SAFETY INFORMATION (CONT'D)

Before or after receiving TZIELD, tell your healthcare provider about all your medical conditions, including if you:

- have a serious infection or an infection that does not go away or that keeps coming back.
- have recently received or are scheduled to receive an immunization (vaccine). TZIELD may affect how well a vaccine works. Tell your healthcare provider that you are receiving treatment with TZIELD before receiving a vaccine.
- are pregnant or plan to become pregnant. TZIELD may harm your unborn baby. Do not receive TZIELD during pregnancy and at least 30 days before a planned pregnancy.
- are breastfeeding or plan to breast feed. It is not known if TZIELD passes into your breast milk and if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive TZIELD. If you are breastfeeding, you may consider pumping and throwing away your breast milk during treatment with TZIELD and for 20 days after receiving TZIELD treatment.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of TZIELD?

The most common side effects of TZIELD include:

- rash
- leukopenia (decrease in white blood cell counts)
- headache

These are not all of the possible side effects of TZIELD. For more information, ask your healthcare provider or pharmacist. You may report side effects to the FDA at www.fda.gov/medwatch or 1-800-FDA-1088, or to Provention Bio at 1-844-778-2246.

Please see Medication Guide and Prescribing Information. Talk to your doctor about TZIELD.

