

IT'S FINALLY TIME TO GET A STEP AHEAD

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

It's possible for you to take control and delay the onset of insulin-dependent type 1 diabetes

TZIELD is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) for people 8 years and older with Stage 2 T1D.

Stage 2 T1D means that you 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.

Stage 3 T1D is when your body can't make enough insulin on its own and may require insulin injections.



Actor Portrayal

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 that 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.

IMPORTANT SAFETY INFORMATION

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

TZIELD may cause serious side effects. These include:

- **Cytokine release syndrome (CRS).** Signs and symptoms may start during the first 5 days of TZIELD treatment and could include fever, nausea, feeling tired (fatigue), headache, muscle and joint pain, or increased liver enzymes in your blood. 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 accompanying Medication Guide and Prescribing Information.

THE IMPORTANCE OF EARLY SCREENING

WHAT IS TYPE 1 DIABETES SCREENING?

Unlike a blood sugar level test, an autoantibody blood screening looks for early signals of autoimmune type 1 diabetes and is used to determine the risk of developing it.

WHO SHOULD CONSIDER GETTING SCREENED FOR T1D?

Anyone can get autoimmune T1D at any age, no matter their family history or diet and exercise choices, but there **are** factors that could increase the risk:

UP TO
15x

The risk of developing autoimmune T1D is **up to 15 times higher** if even 1 other family member has it.



Exposure to certain viruses (like mumps, rotavirus, and coxsackievirus B) or autoimmune conditions (like celiac disease or Hashimoto's) could also mean a higher risk.

HOW CAN YOU OR YOUR LOVED ONE GET SCREENED?

There are several ways to get screened for type 1 diabetes, including at a doctor's office, at certain labs, telehealth services, or with an at-home test kit. A doctor can help you or your loved one decide on the best option.



KNOW THE OPTIONS

See screening options for you or your loved one at TZIELD.com

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TZIELD IS THE FIRST AND ONLY TREATMENT OF ITS KIND



Actor Portrayal

For the first time ever in the treatment of type 1 diabetes, people can act **before** visible symptoms, the risk of serious complications, and the need for insulin.

TZIELD could mean **more time** to prepare for diabetes management:



Counting Carbs



Insulin Injections



Finger Sticks



Cost of Supplies

TZIELD is for people 8 years and older who have Stage 2 type 1 diabetes. There are currently no studies showing the effect TZIELD has on burden of disease.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about TZIELD? (cont'd)

TZIELD may cause serious side effects. These include: (cont'd)

- **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. A decrease in white blood cell counts can happen after your first dose. Your white blood cell counts will start to go back to normal after your fifth dose of TZIELD. Some people may develop longer and more severe decreases in lymphocytes

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WHAT IS TYPE 1 DIABETES AND WHAT ARE ITS STAGES?

Although many think of type 1 diabetes (T1D) as a disease that mostly affects children, it's actually a lifelong progressive autoimmune disease that can happen to anyone, regardless of age, family history, or lifestyle choices.

AUTOIMMUNE TYPE 1 DIABETES AND THE BODY

With T1D, your immune system mistakenly attacks and damages healthy insulin-producing cells called beta cells. Insulin helps convert food to energy in the body. Without insulin, blood sugar level rises, which can lead to life-threatening complications such as diabetic ketoacidosis (DKA).



Learn more about autoimmune type 1 diabetes at TZIELD.com

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about TZIELD? (cont'd)

TZIELD may cause serious side effects. These include: (cont'd)

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.

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THE STAGES OF TYPE 1 DIABETES

There are 3 stages of autoimmune type 1 diabetes. Stages 1 and 2 have no obvious symptoms because the body is still able to make enough insulin. However, in Stage 3, the body is no longer able to make enough insulin to keep blood sugar at a normal level. This is when symptoms are noticed, serious complications can happen, and insulin injections and disease management may become necessary.

Stage 1



The immune system has started attacking **beta cells**



Two or more T1D **autoantibodies** are present



Blood sugar levels are within a normal range



No obvious symptoms



No insulin is needed

Stage 2



Beta cells continue to be attacked



Two or more T1D **autoantibodies** are present



Blood sugar levels are outside of a normal range. This is called **dysglycemia**



No obvious symptoms



No insulin is needed

Stage 3



Beta cells are damaged and can't make enough insulin to regulate blood sugar



Two or more T1D **autoantibodies** may be present



Blood sugar levels are higher than a normal range and there's a risk of complications like diabetic ketoacidosis (DKA). This is called **hyperglycemia**



Obvious symptoms



The body can't make enough insulin on its own, so **insulin injections will eventually be needed**



THE MOST COMMON SIDE EFFECTS OF TZIELD

These are not all the possible side effects of TZIELD. Talk to your doctor and healthcare team for more information or medical advice about side effects.

The clinical trial included 76 people (44 on TZIELD and 32 on placebo).
The median* follow-up time was 51 months.



Rash
(36% of people)



Decrease in white blood cell counts (leukopenia)
(21% of people)



Headache
(11% of people)

TZIELD MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:



Cytokine Release Syndrome
(2% of people)

TZIELD can cause a side effect called cytokine release syndrome, or CRS. Signs and symptoms of CRS include:

- fever
- muscle and joint pain
- headache
- feeling tired (fatigue)
- nausea
- increased liver enzymes in your blood

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



Decrease in White Blood Cells (Lymphopenia)
(73% of people)

TZIELD may cause a drop in a type of white blood cell called lymphocytes. This can affect your body's ability to fight infections. A decrease in white blood cell counts can happen after your first dose. Your white blood cell counts will start to go back to normal after your fifth dose of TZIELD. Some people may develop longer and more severe decreases in lymphocytes.



These are not all of the possible side effects of TZIELD. Talk to your doctor for more information or for medical advice about side effects.

The safety of TZIELD was studied in 5 clinical trials. Side effects were monitored in 773 patients who were given TZIELD and 245 patients who were given placebo. Not all of the patients in these studies had Stage 2 autoimmune type 1 diabetes.

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TZIELD IS CHANGING THE POSSIBILITIES OF TYPE 1 DIABETES TREATMENT

Finally, early-stage type 1 diabetes management is no longer about just waiting for what comes. **It's possible for you to take control of what's next.** TZIELD could mean more time in Stage 2 without the need for insulin injections, more time to learn about eventual symptoms and risks, and more time to get ready for daily management.

THE EFFECTIVENESS OF TZIELD

In a clinical trial, TZIELD was proven to delay progression from Stage 2 to Stage 3 type 1 diabetes for a median* of ~4 years (50 months), compared with ~2 years (25 months) for people who were given placebo.

Time to Onset of Stage 3 Type 1 Diabetes



59%
lower risk

Over the course of a clinical study, the risk of the onset of Stage 3 autoimmune type 1 diabetes was significantly lower for people who were given TZIELD, compared with people who did not take TZIELD.

At the 4-year mark of the study, Stage 3 autoimmune type 1 diabetes was diagnosed in 45% of people who were given TZIELD, compared with 72% of people who were given placebo. Your results may vary.

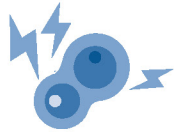
The clinical trial that studied the effectiveness of TZIELD for delaying the onset of Stage 3 T1D included 76 people. The participants had Stage 2 T1D. 44 people in this trial were given TZIELD. 32 people in the trial were given placebo. People in the trial were followed until they were diagnosed with Stage 3 T1D. The median* amount of time that people were followed in the trial 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.

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

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HOW TZIELD WORKS

TZIELD WORKS DIFFERENTLY



Type 1 diabetes is an **autoimmune disease**. It occurs when the immune system attacks **insulin**-producing cells in the pancreas called **beta cells**.



TZIELD may work by turning off the cells in the immune system that attack **beta cells**, which produce **insulin** and are found in the pancreas.



Actor Portrayal

DELAYING THE BURDENS

At Stage 3 of autoimmune type 1 diabetes, the body can't make enough insulin on its own, so taking daily insulin injections will eventually be needed. TZIELD could give people more time to prepare, find the right care team, and live without eventual insulin injections and daily challenges of Stage 3 type 1 diabetes.

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TREATMENT WITH TZIELD

If a doctor decides TZIELD is right for you or your loved one, 2 weeks of treatment now could mean more time in Stage 2 type 1 diabetes for patients 8 years and older when daily insulin injections are not yet needed.

TZIELD IS AN INTRAVENOUS (IV) INFUSION

This means it's given through a needle into a vein in your arm. **TZIELD infusions are given once a day, for 14 days in a row, and take at least 30 minutes to administer.**



14 days



At least 30 minutes long

You will also need some extra time before and after each infusion so a nurse can prepare the infusion and monitor you or your loved one for a short period afterward. During the first 5 days of treatment, you will be given medicines to take before the infusion, which may help reduce symptoms of CRS.

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

A TZIELD COMPASS Navigator can help plan treatment. See page 10.

TALK TO YOUR DOCTOR ABOUT BLOOD TESTS

Your doctor will do blood tests to check your liver and your complete blood counts before you start treatment and during treatment with TZIELD.

IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before receiving TZIELD?

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 keeps coming back
- have recently received or are scheduled to receive an immunization (vaccine). TZIELD may affect how well a vaccine works. Tell your doctor that you are receiving 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 breastfeed. 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



TzielD[®] COMPASS[™]

SUPPORT PROGRAM

Through our personalized program, a COMPASS Navigator can connect you with tools and resources, information on financial assistance options, and one-on-one support from the day you are enrolled.

This means you can get the help you need, when you need it, to support you during the treatment process.

TZIELD COMPASS NAVIGATORS ARE HERE TO HELP WITH:



Personalized Support

TZIELD COMPASS Navigators can answer questions about the program and resources, including how your insurance benefits work, and help you determine out-of-pocket costs.



TZIELD Copay Program

Navigators can provide information about the TZIELD Copay Program,[†] where **eligible patients may pay as little as \$0**, and help you explore other financial assistance options that may be available to you.

[†]Eligibility requirements and terms and conditions apply. Visit Tzielhcp.com/CompassTerms for more information. 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 patients take at the same time as TZIELD or with other facility fees.



Treatment Information

Navigators can help you understand where to get TZIELD infusions depending on your insurance and other factors, plus check in with you once treatment is completed.

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

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Eligibility requirements and terms and conditions apply. Visit Tzielhcp.com/CompassTerms for more information on the terms and conditions.

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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. Talk to your healthcare provider for more information, and tell them about any side effects you notice. You may report side effects to the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

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TALK TO A DOCTOR ABOUT **SCREENING AND TZIELD**

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Actor Portrayal



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type 1 diabetes at TZIELD.com

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