



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

AN OPPORTUNITY TO

Reshape your journey with type 1 diabetes (T1D)

NOW APPROVED for ages 1 and up

TZIELD is FDA-approved to delay the onset of insulin-dependent (Stage 3) T1D in **eligible adults and children aged 1 year and older** with Stage 2 T1D.

Katie, real TZIELD patient

What is TZIELD?

TZIELD is a prescription medicine used to delay the onset of Stage 3 type 1 diabetes, which is when your body cannot make enough insulin on its own and may require insulin injections. TZIELD is for adults and children 1 year 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 or other forms of diabetes.

It is not known if TZIELD is safe and effective in children under 1 years of age.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

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

TZIELD may cause serious side effects, including:

- **Viral Reactivation.** Epstein-Barr virus (EBV) and cytomegalovirus (CMV) are common viruses that may stay inactive in your body after an initial infection. TZIELD may cause these viruses to become active again which, especially in patients with a weakened immune system, can become serious and potentially life-threatening. (continued on next page)

Please see additional full [Prescribing Information](#), including Risk of **SERIOUS SIDE EFFECTS** and [Medication Guide](#).

Understanding autoimmune type 1 diabetes (T1D)

T1D is a lifelong autoimmune disease that affects the body's ability to make insulin, a hormone that turns food into energy and helps keep blood sugar levels stable. Insulin is made in the pancreas by special cells called **beta cells**.

What happens in your body when you have T1D

- In T1D, the immune system **mistakenly attacks and destroys beta cells**, reducing your body's natural ability to make insulin and regulate blood sugar
- T1D progresses in stages and has no obvious symptoms in Stage 1 or Stage 2; you may not even know it's happening
- When enough beta cells are damaged, your body can **no longer produce the insulin it needs** on its own, and that's when daily insulin injections or an insulin pump is needed to regulate blood sugar (Stage 3 and Stage 4)

IMPORTANT SAFETY INFORMATION (cont'd)

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

TZIELD may cause serious side effects, including:

- **Viral Reactivation. (cont'd)** These viral reactivations can happen during treatment with TZIELD and up to 2 months after your last dose. Your healthcare provider will test you for active EBV and CMV infections before treatment with TZIELD. Contact your healthcare provider right away if you develop symptoms of an infection during or after treatment with TZIELD (such as fever, swollen glands, or fatigue).
- **Cytokine release syndrome (CRS).** Signs and symptoms may start during the first 5 days of TZIELD treatment and could include fever, nausea (with or without vomiting), 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.

What a Stage 2 T1D diagnosis really means

Learning that you or your loved one has Stage 2 T1D can come as a surprise. At this stage, you or your loved one may feel fine but **beta cells continue to be attacked and blood sugar levels are abnormal**.

An opportunity to treat T1D in Stage 2 with TZIELD

Managing T1D is no longer just about waiting for symptoms to appear. If diagnosed at the right time, TZIELD offers an opportunity to act while the body is still producing its own insulin. This could give you **more time before Stage 3 T1D, when symptoms appear and daily insulin is needed**.

How does TZIELD work?

TZIELD may slow down the damage to some insulin-producing **beta cells inside the body**.

It is thought to work by targeting certain immune cells that are responsible for the immune system's mistaken attack on insulin-producing beta cells.

To be eligible for TZIELD, you or your loved one must:

- ✓ Be 1 year of age or older with Stage 2 T1D
- ✓ Have tested positive for 2+ T1D-related autoantibodies
- ✓ Have abnormal blood sugar levels
- ✓ Not have type 2 diabetes or other forms of diabetes



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A chance for more time before Stage 3

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Molly and Aubri, real TZIELD caregiver and patient

For people with Stage 2 T1D, TZIELD could mean more time before the stage when daily insulin is needed—providing time to understand T1D and plan next steps in care.

TZIELD can help delay the onset of insulin-dependent T1D

With a single 2-week course of TZIELD, adults and children aged 8 years and older had a median* of 4 years† before the onset of insulin-dependent type 1 diabetes, compared to 2 years with placebo.



4 years

TZIELD

2 years

Placebo

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

†In a clinical trial with TZIELD, people had a median of 4.2 years before the onset of insulin-dependent (Stage 3) type 1 diabetes, compared to 2.1 years for placebo. Results may vary.

The clinical trial included 76 people in the stage right before they become insulin-dependent (Stage 2 T1D). 44 received TZIELD and 32 received placebo. People were followed until they were diagnosed with insulin-dependent T1D (Stage 3). The median* amount of time that people were followed was 51 months (just over 4 years). People not diagnosed with insulin-dependent T1D were followed for different periods of time.

A unique opportunity

Acting now, before T1D progresses to Stage 3 when daily insulin is needed, could make a meaningful difference.

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. 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.

Please see additional full [Prescribing Information](#), including [Risk of SERIOUS SIDE EFFECTS](#) and [Medication Guide](#).

TZIELD has a well-established safety profile studied for over 10 years in clinical trials

TZIELD may cause serious side effects including **viral reactivation (which can be life-threatening)**, cytokine release syndrome, and a decrease in your white blood cell counts. Tell your doctor right away if you develop **fever, swollen glands, tiredness, nausea (with or without vomiting), muscle and joint pain, or headache.**

Certain viral infections, such as Epstein-Barr virus and cytomegalovirus, can come back during treatment with TZIELD and up to 2 months after your last dose. Your doctor will test you for active infections before starting treatment, and monitor you for signs and symptoms of viral reactivation following treatment and for at least 2 months after the last infusion.

To potentially help reduce symptoms of cytokine release syndrome, your doctor will prescribe oral medications for the first 5 days of treatment. For those who experienced a decrease in white blood cell count, these levels typically began to recover after the fifth day of treatment.

The most common side effects of TZIELD in patients 8 years of age and older include:



Decrease in lymphocytes, a type of white blood cell (lymphopenia)
73% of people



General decrease in total white blood cells (leukopenia) 21% of people



Rash 36% of people



Headache 11% of people

The most common side effects seen in children under the age of 8 were vomiting (52%) and diarrhea (30%).

TZIELD was approved by the FDA for children 1 to <8 years of age based on evidence of a previous clinical study with people 8 years of age and older with Stage 2 T1D (including 29 pediatric patients) and an additional safety study in 23 pediatric patients aged 1 to less than 8 years of age with Stage 2 T1D. Side effects were found to be consistent in young children and those 8 years and older.

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

2 weeks of treatment could help reshape your T1D journey

TZIELD is a single course of treatment

A healthcare team will administer TZIELD as an intravenous (IV) infusion in the arm. Infusions are given once a day, for 14 days in a row.

- For adults and children 8 years of age and older, each infusion will last at least 30 minutes
- Children 1 to <8 years of age will be infused over a minimum of 2 hours

Additional time will be needed before and after for preparation and monitoring.

Your or your loved one's doctor will do blood tests to check your liver and complete blood counts before and during treatment. If a scheduled infusion is missed, your healthcare team will continue treatment on the next scheduled day. You will not receive 2 infusions on the same day.

Flexible options to receive care

Site-of-care options for TZIELD infusions may vary depending on location and availability. A doctor will work with you or your loved one to determine the most suitable option, taking into account individual circumstances, preferences, and insurance coverage.

Site-of-care options include:



At home



Infusion center
or doctor's office



Combination



Be inspired by real treatment stories

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"For our family, the healthcare team was a great source of support. They really knew their stuff, and they were very caring and attentive to my son's needs."

—Amanda, real TZIELD caregiver



Amanda and William, real TZIELD caregiver and patient

Hear from the TZIELD Patient Ambassadors

TZIELD Patient Ambassadors are real patients or caregivers of TZIELD patients living with autoimmune type 1 diabetes (T1D) who have personally experienced TZIELD treatment.

Watch TZIELD patients and caregivers share their infusion stories, offering insights and tips on treatment. ▶

Scan the QR code or [click here](https://bit.ly/youtube-infusion) to watch the video at bit.ly/youtube-infusion



IMPORTANT SAFETY INFORMATION (cont'd)

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

TZIELD may cause serious side effects, including:

Your healthcare provider will do blood tests to check for active infections, verify your liver function 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 viral reactivation, or if your blood counts stay too low.

Please see additional full [Prescribing Information](#), including [Risk of SERIOUS SIDE EFFECTS](#) and [Medication Guide](#).

Learn more about what happens before, during, and after treatment with TZIELD. ▶

Scan the QR code or [click here](https://tziield.com/treatment) to learn more at [TZIELD.com/treatment](https://tziield.com/treatment)



By your side throughout the treatment journey

TZIELD COMPASS is a dedicated patient support program designed to guide and assist at every step of the treatment journey, making the TZIELD experience as seamless and supportive as possible.

Just one call can connect you with someone who can:

- Explain insurance coverage and what it means for treatment
- Share information about financial assistance options
- Help identify infusion locations based on insurance and other needs
- Educate about what to expect during infusions and how to prepare
- Provide ongoing check-ins throughout treatment
- Answer questions about the TZIELD COMPASS Patient Support Program and its resources



For more information about TZIELD COMPASS Support, call 1-844-778-2246 Monday through Friday, 8 am–8 pm ET, or email COMPASS@sanofi.com



“Within a day of me reaching out to TZIELD COMPASS, I had a phone conversation. They were so helpful!”

—John, real TZIELD patient

Only your doctor’s office can complete your enrollment in TZIELD COMPASS. The enrollment form requires a patient’s or guardian’s signature, which can be done in person or digitally. Your doctor will submit the completed enrollment form.

Get started at TzielD.com/enroll. [Click here](#) to download the form.

Please see additional full [Prescribing Information](#), including Risk of **SERIOUS SIDE EFFECTS** and [Medication Guide](#).

Financial support and other resources

As little as \$0 copay may be available

With the TZIELD Copay Program, eligible, commercially insured patients may pay **as little as \$0** for treatment.*

You may be eligible for the TZIELD Copay Program if you:

- Have a TZIELD prescription
- Have commercial insurance
- Are a resident of the 50 United States, the District of Columbia, Puerto Rico, Guam, or the US Virgin Islands; and are a patient or caregiver aged 18 years or older

92% of
US patients
with commercial
insurance or
with Medicaid
are covered
for TZIELD.†

TZIELD COMPASS can provide details about this program and help you explore other available financial assistance options if you do not qualify. Scan the QR code or [click here](https://TzielD.com/cost-coverage) to learn more at TzielD.com/cost-coverage



*Coverage varies. \$0 copay available for many with commercial insurance. Check eligibility with TZIELD COMPASS. The TZIELD Copay Program is 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, taxed, or restricted. Sanofi reserves the right to rescind or amend this offer, eligibility, and terms of use at any time without notice. Upon registration, patients receive all program details.

†Formulary data are provided by Managed Markets Insight & Technology, LLC and are current as of 01/2025.

Eligibility requirements and terms and conditions apply. See TzielDhcp.com/CompassTerms for more information.

Connect with a TZIELD Mentor

If you’ve spoken with your doctor about TZIELD, or have been prescribed treatment, you can register to speak one-on-one with a TZIELD Mentor, **a real patient or caregiver of a TZIELD patient**. Reach out to TZIELD COMPASS at 1-844-778-2246, Monday through Friday, 8 am–8 pm ET, or COMPASS@sanofi.com to hear firsthand stories and learn from their personal experiences with TZIELD.

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Take the conversation with your or your loved one's doctor further

Deciding on a treatment often takes more than one conversation. Use the questions in this guide to have a deeper discussion with your or your loved one's doctor and help prepare for your next steps.



Actor portrayal

*"If I could go back, I would absolutely do this again... It meant more time to get comfortable with the diagnosis, better understand my body, and get used to the idea of eventually depending on insulin."**

—John, real TZIELD patient

*There are no data to suggest that TZIELD will have any effect on these outcomes. Individual results may vary.

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 any of the conditions or symptoms listed in the section **"What is the most important information I should know about TZIELD?"**
- have a weakened immune system, including if you have Down syndrome.
- have a serious infection or an infection that does not go away or keeps coming back (chronic).
- 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. If you become pregnant while taking TZIELD, you are encouraged to report your pregnancy to us at our Adverse Event reporting line at 1-800-633-1610 or visit <https://ae.reporting.sanofi>.
- 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.

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:

- decrease in white blood cell counts
- vomiting
- rash
- diarrhea
- headache

These are not all of the possible side effects of TZIELD. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to us at 1-800-633-1610 or visit <https://ae.reporting.sanofi>.

Please see additional full Prescribing Information, including Risk of SERIOUS SIDE EFFECTS and Medication Guide.



Questions to ask your doctor about TZIELD and the infusion process:

- What happens if I decide to wait before I start TZIELD?
- Can you explain how TZIELD may help slow down some of the damage to insulin-producing cells in the pancreas?
- What are the pros and cons of each site-of-care option?
- Which infusion method (daily IV, midline, or PICC)* would be best for my treatment, and what are the benefits and considerations of each option?
- What can we do before treatment to prepare for some of the most common side effects?
- How will my healthcare team monitor side effects?
- Does TZIELD interfere with other medicines or vaccines?
- Will I be able to carry on with activities while I'm receiving treatment with TZIELD?
- Is there anything I should bring with me to each infusion appointment?
- Will I need additional follow-ups after completing TZIELD?

*IV=intravenous; PICC=peripherally inserted central catheter.

Find answers to other frequently asked questions.
Scan the QR code or [click here to read more at TZIELD.com/faq](https://www.tziield.com/faq)



Next steps after getting a prescription for TZIELD

Your doctor is your go-to source for information about TZIELD and will be by your side throughout your treatment journey.

Starting your journey

Once you or your loved one has received a prescription for TZIELD, the next step is working with your doctor to enroll in the TZIELD COMPASS Patient Support Program.

Here's how it works:

- You or your doctor can download the enrollment form at [TZIELD.com](https://www.tziield.com)
- Your doctor will help complete the form with your input and submit it
- Don't forget to carefully review and sign your eConsent to finalize your enrollment

What happens next?

Once you're enrolled, TZIELD COMPASS will reach out to you within 1 business day.

Have questions about cost and coverage or the infusion process?

Whether you're new to infusions or need more details, TZIELD COMPASS is here to guide you every step of the way.



For more information about TZIELD COMPASS, call 1-844-778-2246 Monday through Friday, 8 am–8 pm ET, or email COMPASS@sanofi.com.



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“All I heard was more time before the stage when daily insulin is needed to manage T1D—and to me, that meant everything.”

—Molly, real TZIELD caregiver

Talk to your doctor about delaying the onset of insulin-dependent T1D with TZIELD



Sign up to hear from real patients and receive personalized support to guide your journey with T1D and TZIELD.

Scan the QR code or [click here](https://tziield.com/stay-connected) to sign up at [TZIELD.com/stay-connected](https://tziield.com/stay-connected)

IMPORTANT SAFETY INFORMATION (cont'd)

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