



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

NOW APPROVED for ages 1 year and up

Getting started with TZIELD treatment

Everything to know about TZIELD treatment for people
with Stage 2 type 1 diabetes (T1D)

Molly and Aubri, real TZIELD caregiver and 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**.

"The chance for our son to have any portion of time before the stage when daily insulin is needed means everything."

—Amanda, real TZIELD caregiver



Amanda and William, real TZIELD caregiver and patient

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.

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

Your proactive choice to help reshape your T1D journey

Whether you or your loved one is about to start TZIELD or you're simply learning about the treatment process, you're in the right place.

Choosing to treat T1D with TZIELD is a courageous step that allows you to act before symptoms appear, while your body can still make enough of its own natural insulin.

This brochure can help guide you through the TZIELD infusion experience and help you or your loved one feel more informed and prepared. Because confidence in your treatment starts with the right support.

What you'll find inside

- **Information about TZIELD:** A refresher on how TZIELD works in the body and its efficacy and safety
- **Infusion planning and tips:** See what to expect before, during, and after treatment, plus practical ways to help make each infusion day more comfortable
- **Support resources:** Explore the TZIELD COMPASS Patient Support Program and its resources, which are there to help you every step of the way

Take a moment to remember why you chose TZIELD



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Katie, real TZIELD patient, and her kids

Starting a treatment for the first time can be overwhelming, but it can help to keep in mind why more time matters for you or your loved one. Two weeks of treatment with TZIELD could mean more time before Stage 3, 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.



*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.

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 responsible for the immune system's mistaken attack on insulin-producing beta cells. TZIELD is a targeted treatment and is not an immunosuppressant.

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.

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.





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

A guide to the TZIELD infusion process

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Injection | 2mg/2mL

Actor portrayal

TZIELD is a single, 2-week course of treatment

-  It is given **once a day, for 14 days in a row**, by a healthcare team member
-  **TZIELD is an infusion**, which is a method of delivering medication through a vein in the arm over a period of time
-  For adults and children 8 years of age and older, each infusion will last **at least 30 minutes**
-  Children less than 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. If a scheduled appointment is missed, your or your loved one's healthcare team will resume treatment on the next scheduled day. You will not receive two infusions on the same day.

Where you can receive TZIELD

There are 3 different location options where you can receive TZIELD. Where you receive your infusion can be based on preference, but it's also determined by your insurance coverage. No matter where you receive it, a nurse will safely administer treatment and monitor you under your doctor's guidance.

 At home	 Infusion center or doctor's office	 Combination
<ul style="list-style-type: none">• Infusion nurse administers treatment in the comfort of your own space• Fits into your routine	<ul style="list-style-type: none">• Support from on-site healthcare team• Access to in-person support	<ul style="list-style-type: none">• Combines at-home and on-site care• Flexibility to choose what works best for you

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

How you can receive TZIELD

Your or your loved one's healthcare team will administer TZIELD as an infusion through the arm, but there are 3 different infusion methods. Your or your loved one's doctor will help determine which one is most suitable.



Peripheral Line: Each day, a new needle is placed into a vein in the arm and often removed after each infusion.

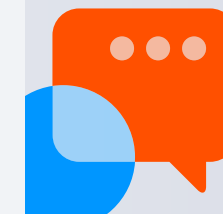


Midline Catheter: A thin, soft tube is placed into a vein in the upper arm and typically stays in place for the entire treatment, for fewer needle sticks. It is removed when the 14-day treatment is over.



Peripherally Inserted Central Catheter (PICC): Similar to a midline, a PICC line can also be placed in a vein in the arm for the duration of treatment.

If you and your doctor decide on a midline or PICC, ask whether it will be placed on or before your first infusion day. You may need to schedule an extra appointment to have it placed.



Visit our Infusion Support Center for guidance and resources to help you or your loved one prepare for TZIELD. Scan the QR code or [click here to learn more at TZIELD.com/treatment](#)



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.

Preparing together: What to expect before TZIELD



John, real TZIELD patient, and his son

IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before receiving TZIELD?

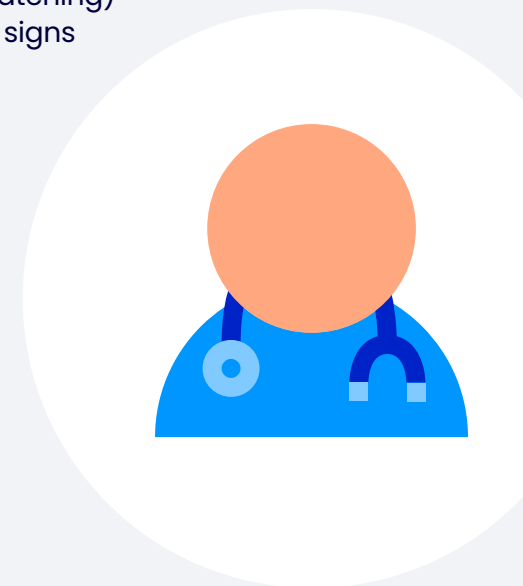
Before or after receiving TZIELD, tell your healthcare provider about all your medical conditions, including if you:

- 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. (continued on next page)

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

Your or your loved one's endocrinologist will schedule a “pretreatment visit” where they will:

- Discuss where and how you'll get TZIELD
- Order testing for **active viral infections** (which can be life-threatening) of EBV and CMV before starting treatment, and will monitor for signs or symptoms of viral reactivation during and after treatment
- Order pre-infusion medication and lab work. Pre-infusion medications will be taken for the first 5 days of your infusion
- 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
- Discuss any current medications you may be taking and the timing of any recent or upcoming vaccinations, as treatment with TZIELD may impact how well they work
- Let your healthcare team know if you've recently had a cold or a serious or chronic infection, or if you have a weakened immune system, including if you have Down syndrome, as this may impact treatment
- Confirm your infusion dates and start times
- Answer any additional questions you have



If you have questions about insurance, infusion logistics, or what to expect, contact the TZIELD COMPASS Patient Support Program for guidance.



“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

An overview of the

14-day treatment

Treatment begins

The healthcare team will take your or your loved one's vitals, like temperature and blood pressure, each day before and after the infusion. For the first 5 days, oral medications will also be given before infusion to help reduce potential side effects.*†

Dosage increases

The TZIELD dose is personalized based on height and weight and will gradually increase over the first 5 days.

Day 5 and beyond

From days 5 to 14, your TZIELD dose will stay the same.

Treatment is complete!

Once all 14 TZIELD infusions have been completed, your healthcare team will schedule follow-up visits to discuss the right post-treatment monitoring and care plan for you or your loved one.



What if I miss an infusion?

If a scheduled appointment is missed, your or your loved one's healthcare team will resume treatment on the next scheduled day. You will not receive two infusions on the same day.

Every person's TZIELD experience is different

While everyone receives one infusion a day for 14 days in a row, how each day feels can vary. Your healthcare team will monitor you or your loved one each day, including for viral reactivation, and help manage any side effects that may arise. Notify your healthcare team right away if you or your loved one experiences any side effects.*††

*For more information on side effects, see page 5.

†In some cases, your or your loved one's care team may prescribe oral medications to help manage symptoms of side effects beyond the first 5 days.

††TZIELD treatment may be stopped temporarily or permanently due to liver problems, serious infections, or low blood cell counts.

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:

- 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.



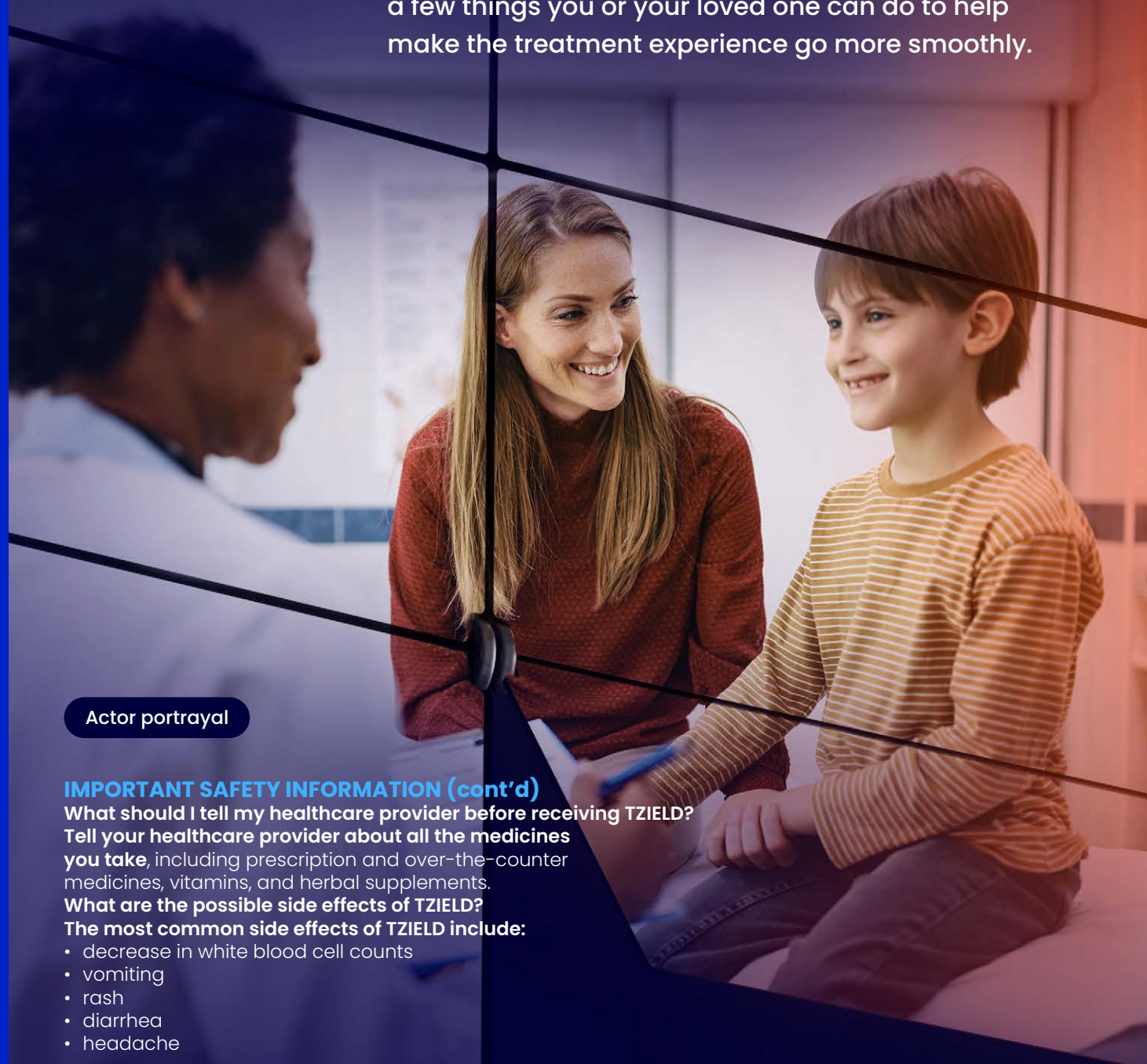
TZIELD COMPASS is your resource for care, clarity, and connection— including the TZIELD Mentor Program to connect with real patients and caregivers of real patients.

Give them a call Monday through Friday, 8 am–8 pm ET, at 1-844-778-2246, or email at COMPASS@sanofi.com (see page 16 for more info).

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

Make the most of your infusion experience

Everyone's infusion journey is different, but here are a few things you or your loved one can do to help make the treatment experience go more smoothly.



Actor portrayal

IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before receiving 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

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

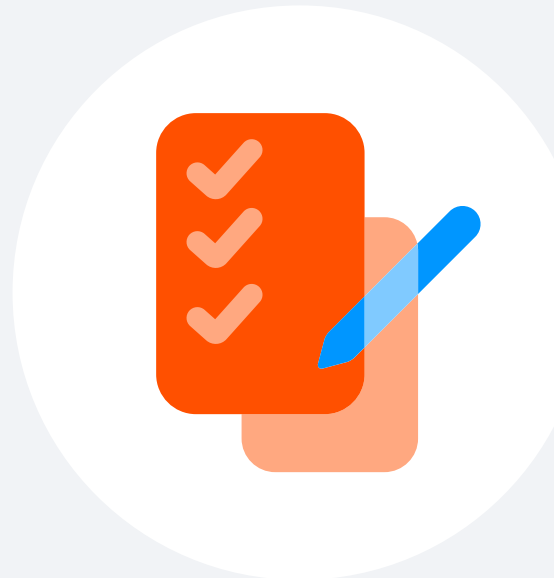
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The night before your infusion:

- Confirm your or your loved one's infusion date and start time
- Get a good night's sleep

The day of your infusion:

- Dress comfortably: Wear something with short or loose-fitting sleeves. Consider bringing a jacket in case you or your loved one gets chilly
- Eat a nourishing meal and drink lots of water
- Have water, snacks, entertainment, and device chargers on hand
- Bring any items you find useful
- As you receive TZIELD, pay attention to how you or your loved one feels and inform your healthcare team of any concerns



Tips if you're traveling to your infusion location:

- Invite a friend or family member to come along for support and drive you or your loved one, as you may be tired following treatment
- Plan the route to the infusion location and research where to park
- Plan to arrive early for infusion preparation. It's a good idea to allow extra time for travel to your infusion site in case of traffic
- If staying overnight, confirm hotel reservations and research new restaurants to try while you're away from home



"By the end of the treatment process, my endocrinologist and the healthcare team were basically family."

—William, real TZIELD patient

You've completed treatment! Now what?

Congratulations, you did it! Now discover what happens after you finish treatment.



John, real TZIELD patient

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of TZIELD?

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](#).



After your TZIELD infusion:

Your or your loved one's endocrinologist will:

- Discuss any side effects you or your loved one may be experiencing and monitor for signs and symptoms of infection. You or your loved one will also be monitored for viral reactivation for at least 2 months post treatment.
- Advise on when you can return to your **normal daily activities**—though most people should be able to resume daily activities at the end of each treatment day
- Determine the right **post-treatment care plan**, including how often to schedule check-ins to manage T1D going forward
- Order **post-infusion lab work and monitor your blood sugar levels** to see how you or your loved one is responding to treatment over time



Next steps:

- Completing treatment is a big milestone and you or your loved one should be proud
- Get in touch with **TZIELD COMPASS** to answer any TZIELD questions you may have
- Stay in touch with your endocrinologist and let them know if you notice any early T1D symptoms or changes over time

Encourage family and friends who are at risk of T1D to talk to their doctors about autoantibody (AAb) screening

AAb screening is the first step in detecting T1D before symptoms appear, allowing time to monitor and potentially help delay the onset of insulin-dependent T1D with TZIELD.

Risk factors for T1D include:



A family history of T1D



Certain autoimmune diseases (including Graves', Hashimoto's, and celiac disease)

Share the power of early T1D screening with family and friends.

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





Support before, during, and beyond treatment

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

Just one call can connect you with someone who can:

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



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

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.

Financial support and other resources

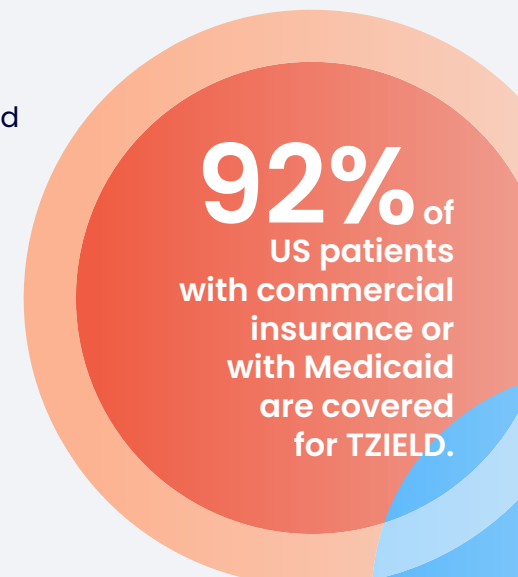


As little as \$0 copay may be available

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



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 to learn more at TZIELD.com/cost-coverage](https://www.tziield.com/cost-coverage)

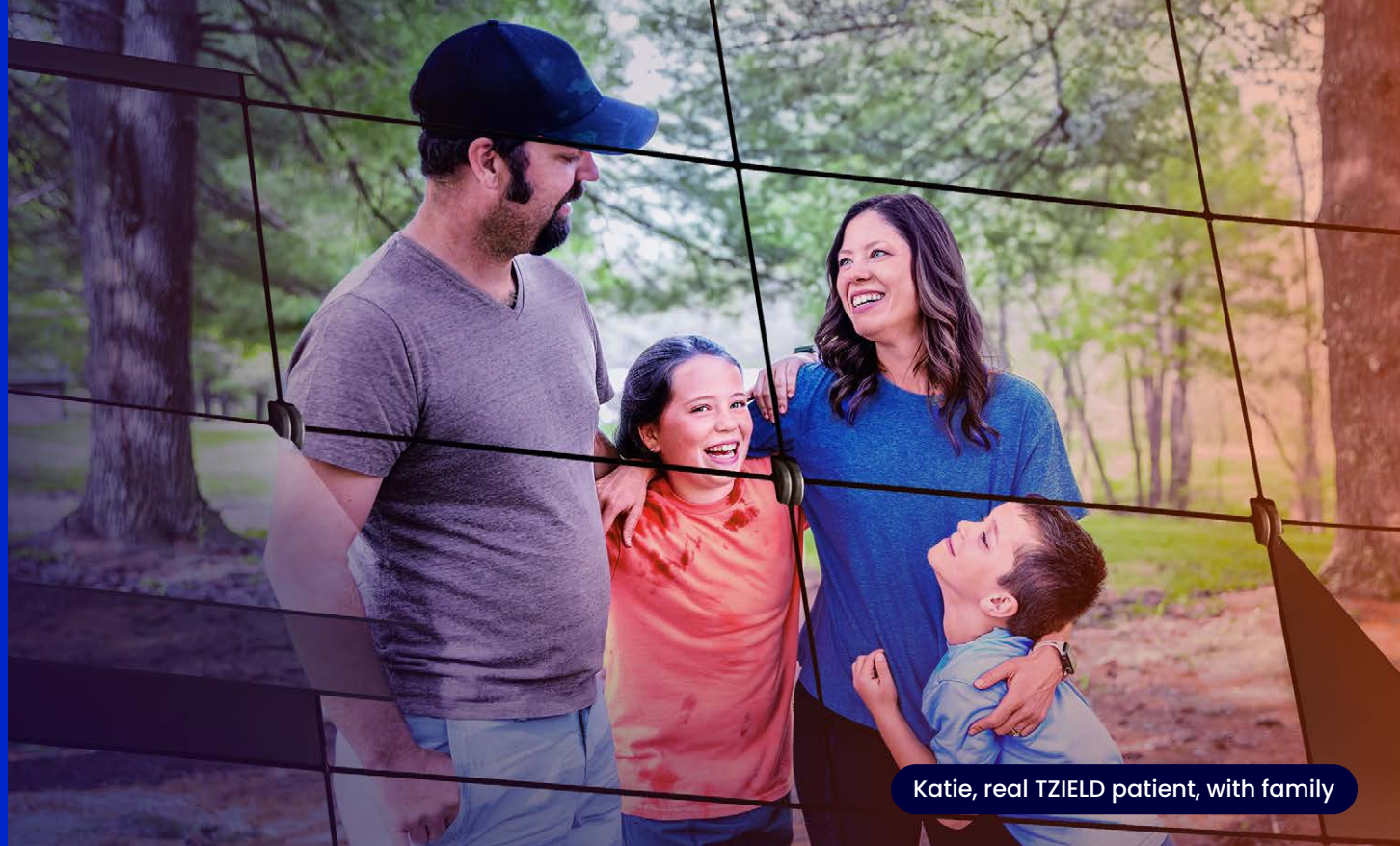


*Coverage varies. \$0 copay available for many with commercial insurance. Check eligibility with COMPASS. The TZIELD Copay Program is not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs including any state pharmaceutical assistance 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.

Eligibility requirements and terms and conditions apply. See [Tziieldhcp.com/CompassTerms](https://www.tziieldhcp.com/CompassTerms) for more information.

Connect with a TZIELD Mentor

If you want to learn more about the TZIELD infusion or have additional questions throughout 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.



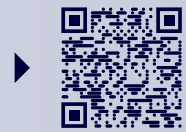
Katie, real TZIELD patient, with family



Molly and Aubri, real TZIELD caregiver and patient

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Watch real TZIELD patients and caregivers share their infusion stories—offering insights, reassurance, 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



Sharing your story can make a difference

Once you have completed treatment, consider becoming a part of the TZIELD Ambassador Program.* Real patients and caregivers are such a great source of inspiration and education for other people who are preparing for treatment with TZIELD. TZIELD Ambassadors share their stories through activities that may include videos, in-person events, or one-to-one phone conversations. If you're interested in learning more, email TIDstories@vprpop.com or call 1-855-212-4267.

*TZIELD Patient Ambassadors are sponsored by Sanofi and are not healthcare providers. For medical questions, talk to your doctor.

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

You're not alone. There is a world of support available to you in whatever form you need, from online resources to in-person support groups. Below are a few helpful organizations to start exploring.

Get more T1D support:

Breakthrough T1D (formerly JDRF): breakthrough1d.org

American Diabetes Association: diabetes.org

Beyond Type 1: beyonddiabetes.org

Taking Control Of Your Diabetes: tcoyd.org

Children with Diabetes: childrenwithdiabetes.com

These support resources are provided for convenience and do not represent a recommendation or endorsement by Sanofi.

Your journey starts today

Look inside the pocket for stickers to be used on this page.

Pre- infusion	Day 1	Day 2	Day 3	
Day 4	Day 5	Day 6	Day 7	
Day 8	Day 9	Day 10	Day 11	
Day 12	Day 13	Day 14	Post- infusion	

If you miss a scheduled infusion, you or your loved one's healthcare team will continue treatment on the next scheduled day. You will not receive 2 infusions on the same day.

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

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