

INFUSION CONSIDERATIONS WITH DISEASE-MODIFYING THERAPIES FOR TYPE 1 DIABETES (T1D)

PATIENT AND CAREGIVER RESOURCES



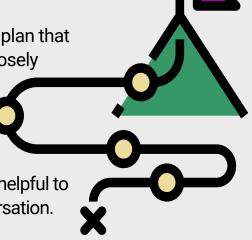


Preparing to Start Treatment with *Teplizumab*

Your Health, Your Decision

Shared decision-making is the key to creating a treatment plan that fits your needs, preferences, and goals. When you work closely with your healthcare provider, it becomes easier to stick to the plan, which increases the likelihood of success.

 Be sure to discuss any concerns or questions before starting treatment with teplizumab, including safety information and potential side effects. Some people find it helpful to make a list to ensure they cover verything during the conversation.



Important Safety Information

• Make a list of things to talk about with your healthcare provider, including the important safety topics below, along with any other worries or questions you may have.

Vaccines

 Certain vaccines should be avoided before and up to one year after receiving teplizumab. Your doctor will inform you if you must catch up on any vaccines before starting treatment.



They will also guide you on which vaccines should be avoided and for how long after your treatment with teplizumab. Following these instructions closely is essential, as the timing is critical!

Pregnancy

 Teplizumab should not be used if you are pregnant or planning to become pregnant within one month of starting treatment.



 If you think you might become pregnant during your treatment course, speak with your healthcare provider immediately

Breastfeeding

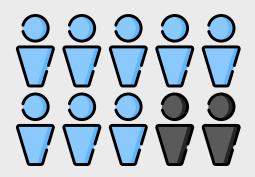
- There is no clear information about whether teplizumab enters breast milk or if it could harm a breastfed baby.
- If you are breastfeeding, talk to your healthcare provider about the best way to feed your baby while receiving teplizumab.



Possible Serious Side Effects:

White Blood Cell Changes

Teplizumab works by adjusting your immune system, which can cause a decrease in white blood cells, particularly a type called lymphocytes. This is common, occurring in about 8 out of every 10 patients during treatment.





Why does it happen?

Lymphocyte counts typically drop to their lowest point around the 5th day of the 14-day treatment.

How long does it last?

• Most people start to see their lymphocyte levels recover after day 5, and they usually return to normal within 2 weeks of completing treatment.

Even though a drop in white blood cells is common with teplizumab, it's usually temporary. Your healthcare provider will monitor your blood counts to keep everything on track.

Cytokine Release Syndrome

Teplizumab works by interacting with your immune system. In some people, this can cause a temporary reaction called **cytokine release syndrome (CRS)**. It's not an infection and isn't contagious—it's your body's immune response to the medicine.

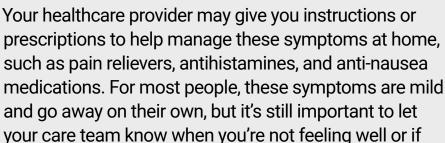
You may feel like you're coming down with something. Symptoms can include:

- Fever
- Nausea or upset stomach
- Headache
- Muscle or joint pain
- Feeling tired or achy
- Lab changes that your care team will monitor



When does it happen?

- Usually, during the first few days of treatment, as your dose increases.
- Symptoms often start the evening after the first infusion and improve over the next few days.
- Symptoms may show up any time during treatment and can last up to 4 weeks after your last dose.



anything feels worse than expected.

Treatment Schedule

Your treatment with teplizumab will last for 14 consecutive days. It's essential to attend all scheduled infusion appointments. If you need to miss an infusion, notify the infusion center immediately so they can help you get back on track and maintain your treatment schedule.

You will have blood tests (labs) done before, during, and after treatment with teplizumab to monitor for side effects like low white blood cell count (leukopenia) and elevated liver enzymes from CRS. Some infusion centers can draw labs when the IV is placed during your infusion. If your center doesn't do this, be sure to get your labs done as instructed by your provider to avoid disrupting your treatment schedule.

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Complete Required Testing

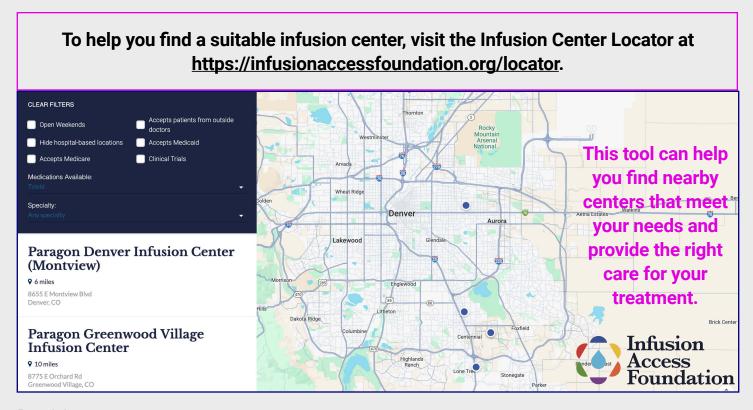
If your provider orders lab tests to check for infections or other conditions that might affect your treatment with teplizumab, get them done as soon as possible. The infusion center may need these results before processing your referral and scheduling your appointment, so getting them done quickly helps avoid delays.

Find a Site of Care

When choosing a site for your infusion, it's essential to consider several factors to ensure your treatment plan is both practical and affordable. Infusions can be given at various locations, including:

- Hospital outpatient department
- Office-based infusion suites
- Freestanding infusion centers

Before deciding, check with your insurance company to understand how costs may vary across different care settings. For example, an infusion at a hospital outpatient department can cost 2-3 times more than the same treatment at an office-based or freestanding infusion center. This cost difference can significantly impact your out-of-pocket expenses, so it's a good idea to explore all your options.



Contact the Infusion Center

Reach out to the infusion center before your appointment to learn what to expect. This can help reduce anxiety and set clear expectations for your appointment. You may consider asking questions like:

- How long does an appointment usually take?
- Will I need any pre-infusion medications or post-infusion monitoring?
- Can I have a friend/care partner stay with me during my appointment?
- Should I arrange for someone to drive me home?
 [Your provider may order additional medications to be given before your infusion that may make you too sleepy to drive yourself home]

"What should I wear to my infusion? Will I need to roll up my sleeves or remove clothing?"

"Will there be snacks, drinks, or a place to store my own food?"



Explore Financial Assistance

Check the manufacturer's website to learn about patient access programs and financial assistance available to help you afford your medications. Your prescriber's office or infusion center can also help you find this information. If you have concerns about your ability to afford the new medicines, tell your healthcare team—they want to help!

"Where can I find financial resources or support to help cover the cost of my infusion?"

Find Support

Navigating treatment for type 1 diabetes can feel overwhelming at times, but you're not alone. In addition to the support provided by your healthcare team, the manufacturer may offer programs to help patients better understand their insurance coverage, explore financial assistance options, and receive personalized support throughout treatment.

Patients may also find support through online communities and advocacy organizations related to type 1 diabetes. Groups like the **Infusion Access Foundation** can help you better understand your treatment options and connect you with resources to support your access to care. These platforms also offer shared experiences, advice, and encouragement from others undergoing similar treatments.

And remember—your healthcare team is always a valuable source of guidance and support as you begin your treatment with teplizumab.



Preparing for Infusion Day

Illness & Rescheduling

- Teplizumab should not be given if your body is already working to heal a severe infection. If you have an active infection or otherwise become ill before your appointment, call the infusion center to discuss whether it might be best to reschedule.
- If you need to miss a dose, you will resume daily dosing when your healthcare team determines it's safe, and the infusion center will work with you to reschedule any missed treatments so you still receive all 14 doses.





Hydrate!

- Start drinking plenty of extra fluids like water for a day or two prior to your appointment; being well hydrated can help make your veins more easily accessible.
- If you have been told to limit your fluid intake due to another medical condition, check with your provider before drinking extra fluids.

Pack the Essentials

List of medications and allergies:

Include prescription medicines, over-the-counter drugs, vitamins, and supplements. Be sure to note your doses and when you take them.

Insurance card and identification:

Bring your insurance card and a form of ID (eg, driver's license).

Entertainment:

Bring something to help pass the time, like:

- earbuds to listen to relaxing music or your favorite podcast
- puzzles, like a crossword or sudoku
- a tablet to watch a show or movie
- a good old-fashioned paper book!

Comfort items:

 Think about what will make you feel relaxed and at ease during your infusion, like a cozy lap blanket or soothing playlist.





Pick out comfy clothes

- Choose some comfortable clothes for your infusion, ensuring your shirt sleeves can be rolled up easily to allow access to your arms and veins.
 - Some people feel chilly during their infusion because the medication is room temperature, much cooler than body temperature. Wearing warm socks and loose layers—like a light jacket, hoodie, or blanket scarf—can help you stay cozy and comfortable throughout your appointment.
- Taking a few moments to plan your outfit can go a long way toward making you comfortable.

Try to get a good night's sleep

 Being well-rested can help you feel more relaxed and make it easier to manage nervous feelings.

Getting a good night's sleep before your infusion day can help your body feel more prepared and your mind more at ease. When you're rested, it's often easier to focus, stay calm, and handle any unexpected moments that come up.

Even a short nap or quiet time the night before can make a big difference.











What to Expect During Teplizumab Infusions

This section provides a general guide to what you can expect during your teplizumab infusion. Remember that every infusion center may have slightly different processes, so be sure to check with your specific center for any details that may apply to your treatment.

A Typical Teplizumab Infusion Visit

- At the start of your appointment, a nurse¹ will review your list of medications and allergies to make sure you are healthy enough to receive your treatment.
 - They may ask questions about how you're feeling, check your vital signs like blood pressure and temperature, and measure your weight to calculate your dose.
- Next, the nurse will place a small intravenous catheter (IV) into a vein in your arm or hand. You may feel a quick pinch when the needle is inserted, but after a moment, it should resolve, and you shouldn't feel discomfort afterward.
- A bandage will hold the IV in place for your treatment. If your IV site hurts or leaks during your infusion, inform your nurse immediately!
- For at least the first five infusions, you will be given premedications about 30 minutes before the infusion to provide them with time to work in your body. These may include pain relievers, antihistamines, and anti-nausea medications to help prevent any side effects during the infusion.
- You may need to wait a few minutes while your medication is mixed, as this step can't be done beforehand. Once it's ready, the nurse will attach the tubing to your IV, and the medication will slowly flow into your bloodstream.
- During the infusion, the nurse will recheck your vital signs and ask how you feel. If you notice anything unusual during your infusion, even if you're unsure if it's a symptom of an infusion reaction, tell your nurse immediately.



Did you know..

While you're getting an infusion, there isn't actually a needle in your arm! Sometimes people worry about keeping their arm completely still because they imagine a sharp needle in their vein.

But once the IV is in place, the needle is removed, and only a tiny flexible plastic tube stays in. The size of the tube is about the thickness of a mechanical pencil lead (about 0.5 mm).





¹This guide refers to the clinician administering infusions as a nurse, but depending on state regulations, infusions may be given by other qualified healthcare professionals.

It's important to let your nurse know immediately if you experience any of the following:

- Feeling hot or flushed
- Dizziness or lightheadedness
- Tightness in your chest or trouble breathing
- Headache or muscle aches
- Any other unusual symptoms



During the infusion:

Depending on the infusion center's policy, you may be asked to stay for a short time (30–60 minutes) after the infusion to ensure your body tolerated it well. During this time, pay attention to how you're feeling and let your nurse know if you experience any unusual symptoms.



When you're ready to leave, the nurse will remove your IV and free you to go! You may want to relax at home for the rest of the day, but maybe not! Everyone responds to medications differently. Listen to your body.



Before you leave:

 Make sure you know when your next infusion appointment is scheduled.



 Ask your nurse or healthcare provider how to manage any side effects you may experience after the infusion, such as headache or nausea; and,



 Be sure to ask about any signs or symptoms that prompt you to contact your healthcare provider or seek medical help immediately.



It's normal to feel overwhelmed by all the information, but try to see this as a short-term investment in your long-term health. Teplizumab allows you to take control of your type 1 diabetes in a way that previous generations couldn't—one infusion at a time.



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Discharge Instructions After Your Teplizumab Infusion

Resuming Normal Activities

After your infusion, you can generally resume your normal activities. Some people feel tired and prefer to rest, and some don't! It's okay to resume your routine if you feel up to it—just listen to your body and rest when needed.

IV Site Care

Bruising and mild discomfort at the IV site are common and should disappear in a few days. You may use a cold compress for comfort today. After that, applying warmth (such as a heating pad) can help with any bruising. Be careful not to freeze or burn the skin.



If you notice changes near your IV site, such as pain, redness, drainage, numbness or tingling, or any other concerning symptoms, contact your healthcare provider.

Side Effects

Teplizumab works by interacting with your immune system. This can cause a temporary reaction called **cytokine release syndrome (CRS)** in some people. It's not an infection or contagious—it's just your body's immune response kicking in. CRS is usually mild and goes away independently, but it can make you feel tired or achy for a few days. In rare cases, it can be more serious. Your health-care provider may have given you instructions or prescriptions to help manage symptoms at home, such as:

- Acetaminophen (Tylenol) or ibuprofen (Advil) for fever, headache, or body aches
- Antihistamines for rash or itching
- Anti-nausea medications if you're feeling sick to your stomach



Get medical attention right away if you experience new or concerning symptoms, such as:

- Dizziness or lightheadedness
- Trouble breathing
- Itching, swelling, or hives (raised, itchy areas of skin)
- Swelling of the hands, face or mouth
- Wheezing (noisy breathing that may sound musical or like whistling)



If you have any questions or concerns after your infusion, contact your healthcare provider or infusion center.

^{*}This is not a complete list of possible symptoms. Call your medical provider for any symptoms that are severe or concerning to you.