DETECT 1D

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

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CLINICIAN RESOURCES

NICA NATIONAL INFUSION CENTER ASSOCIATION

Teplizumab Infusion Clinician Guide

Disclaimer

This guide is intended to serve as an educational and informational resource only. It does not constitute medical or legal advice, nor is it a substitute for individualized clinical judgment, institutional policy, or regulatory guidance. While the National Infusion Center Association (NICA) has made every effort to ensure the accuracy and relevance of the information provided, NICA assumes no responsibility or liability for any errors, omissions, or outcomes resulting from the use of this guide. Implementation of any recommendations is at the sole discretion of each facility. Providers are encouraged to consult applicable federal, state, and local regulations, professional guidelines, and subject matter experts when developing or modifying infusion services. Because standards of care and regulatory requirements may evolve, users should verify that practices remain current and evidence-based.

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Introduction

This guide is intended to support infusion clinicians and care teams in the safe and effective administration of teplizumab-mzwv for patients with stage 2 type 1 diabetes. It outlines practical considerations for intake, preparation, administration, monitoring, and follow-up, incorporating current clinical guidance, product labeling, and lessons learned from real-world implementation. While this guide is not a substitute for clinical judgment or regulatory guidance, it is designed to help standardize processes, reduce delays, and promote a positive treatment experience for patients and families.

Pre-Infusion

1. Medical Necessity and Eligibility

a. Before initiating teplizumab, confirm that the patient meets the approved indication and clinical criteria for treatment. Refer to the **Referral Checklist** for guidance on diagnostic testing and required documentation.

b. In addition to clinical appropriateness, ensure that all payer-specific requirements—such as documentation of medical necessity and prior authorization—have been addressed.

2. Needs Assessment

a. Conduct a structured assessment of the patient's and/or caregiver's educational needs prior to treatment initiation. This should include identifying any preferred learning styles, health literacy levels, and potential communication barriers, such as language, cognitive delays, or sensory sensitivities. Use this information to guide how education is delivered and documented.

b. Provide interpreter services and accessible formats when needed, in accordance with language assistance and accessibility policies.

3. Patient/Caregiver Education

a. Provide verbal and written education about teplizumab, including an overview of the infusion process, potential side effects, signs of cytokine release syndrome (CRS), lab monitoring requirements, and what to expect during and after treatment.

b. Share a copy of the FDA-approved patient medication guide, and review with the patient and/or caregiver, allowing time for questions and discussion. Reinforce education at each visit, particularly in multi-day treatment courses.

c. Ensure information is presented in a developmentally and culturally appropriate manner.

4. Informed Consent and Assent

a. Obtain informed consent from the patient or legal guardian in accordance with federal, state, and facility policies. For pediatric patients, obtain age-appropriate assent when possible, ensuring the child has a chance to participate in understanding the treatment in a way they can comprehend.

b. Consent should include acknowledgment of treatment purpose, potential risks and side effects, expected outcomes, and available alternatives. Ensure documentation of consent is completed and stored in the medical record prior to the first infusion.

5. Medical History & Baseline Assessment

a. Measure and record weight (use this first weight to calculate each daily dose) and height.

b. Hold infusion and notify provider for any of the following contraindications:

i. Abnormal vital signs

ii. Active serious infection or chronic active infection, other than localized skin infections

iii. Signs/symptoms of cytokine release syndrome (CRS) following previous infusion (fever, nausea, fatigue, myalgia, arthralgia)

iv. Recent vaccination:

1. Live-attenuated vaccine within the last 8 weeks.

2. Inactivated or mRNA vaccine within the last 2 weeks.

v. Possibility of pregnancy. Perform a urine pregnancy test for patients of reproductive potential prior to the first treatment.

vi. Abnormal lab values (see table below for recommended monitoring frequency):

1. Lymphocyte count less than 1,000 lymphocytes/µL

2. Hemoglobin less than 10 g/dL

3. Platelet count less than 150,000 platelets/µL

4. Absolute neutrophil count less than 1500 neutrophils/µL

5. Acute Epstein-Barr virus (EBV) or cytomegalovirus (CMV)

A full set of vital signs includes:

- Temperature
- Blood pressure
- Heart rate
- Oxygen saturation
- Respiratory rate

6. Premedicate

a. To reduce the risk of cytokine release syndrome (CRS), for the first 5 days of treatment premedicate with antipyretics (NSAIDs or acetaminophen), antihistamines (use second-generation antihistamines due to overall tolerability and safety), and/or antiemetics 30 minutes prior to the start of the infusion and per protocol/prescriber order.

b. Based on the patient's response to treatment, consider extending the premedication period as appropriate and based on the prescriber's order.

It's important to note that first-generation antihistamines like diphenhydramine can cause side effects, such as sedation and dizziness, which may mimic or exaggerate mild infusion-related reactions, potentially complicating clinical assessment. Diphenhydramine also carries the risk of paradoxical excitation or agitation, especially in pediatric patients, which can increase distress and disrupt care delivery. These considerations suggest that second-generation antihistamines, which have a more favorable side effect profile, may be preferable in some cases. Clinicians should weigh the benefits of diphenhydramine's H1-blocking potency against these potential drawbacks and consider whether a non-sedating second-generation agent may offer better tolerability, especially in pediatric patients.

7. Recommended Assessment

a. The prescriber must indicate whether tests should be processed STAT for same-day review prior to treatment, or as routine for review before the next scheduled infusion.

	Physical Exam	Vital signs	CBC w/ diff	BMP	AST/ALT/ BIli	Infectious agents	Urine preg	Pre-meds
Pre-Rx	✓	✓	✓	✓	✓	✓		
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		✓	✓		✓			

Table adapted from: Mehta, S. et al. (2024). Pediatric Endocrine Society statement on considerations for use of teplizumab (Tzield™) in clinical practice. Hormone Research in Paediatrics.

8. Calculate Dose:

a. Use measured weight from Day 1 and height to calculate the body surface area (BSA):

> Because teplizumab dosing is based on body surface area (BSA), infusion centers must measure both **height and weight**—which may be a departure from typical workflows that only require weight. If your site does not routinely measure height, be sure to obtain appropriate equipment (such as a stadiometer or measuring tape) to ensure accurate BSA calculations.

i. Use the Mostellar BSA formula to calculate BSA:

$$m^2 = \sqrt{\frac{weight\ (kg)\ x\ height\ (cm)}{3{,}600}}$$

ii. Use the BSA to calculate each daily dose:

Day 1: 65 mcg x (calculated BSA)

Day 2: 125 mcg x (calculated BSA)

Day 3: 250 mcg x (calculated BSA)

Day 4: 500 mcg x (calculated BSA)

Days 5-14: 1,030 mcg x (calculated BSA)

iii. Calculate the required volume of teplizumab-mzwv

1. Dose in mcg ÷ 100 mcg = *volume (mL)*

2. Round to the nearest tenth (e.g., 0.6 mL).

> Large adults with BSA ≥1.94 m² will require more than one vial per dose on days 5–14.

9. Vascular Access

a. Obtain vascular access or assess the patency of existing vascular access device per organizational policy.

Medication Preparation

1. Preparation Area

a. Choose a designated medication preparation area that is clean, dry, uncluttered, hard, non-porous surface that can be disinfected prior to use.

b. If the designated area is within 3 feet of a sink, a splash guard is required to help prevent the risk of microbial contamination.

c. This area is free from contamination sources such as food, vermin, visible and non-visible microbial contamination (e.g., rust, glass particles or shavings, hair), and obvious contamination sources such as standing water and biohazardous materials or specimens.

d. Disinfect the surface before starting preparation.

Before beginning preparation:

a. Perform hand hygiene

b. Gather supplies as applicable based on method used (see below)

c. Follow Aseptic Non Touch Technique (ANTT®) throughout preparation procedure.

2. Withdraw Medication

a. Perform hand hygiene and don clean gloves.

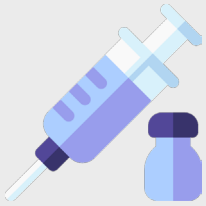
b. Inspect teplizumab vial: solution should be clear, colorless, and particulate-free. Confirm expiration date.

c. Remove the flip-top cap and disinfect[1] the vial septum.

d. Withdraw 2 mL of teplizumab into a 3 mL syringe.

e. Remove and discard the needle from the syringe.

f. Attach a sterile dead-end cap.

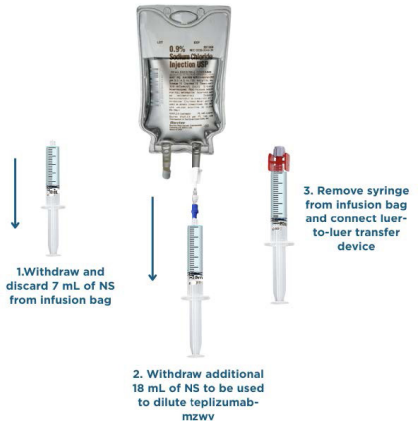


[1] vigorously scrub with antiseptic and allow to completely air dry.

3. Initial Dilution

a. Dilute 2 mL of teplizumab in 18 mL of 0.9% Sodium Chloride to prepare the intermediate solution of 2 mg/20 mL using one of the following options:

Preparation Per Manufacturer's Instructions		Alternative Preparation Method*** Minimizes contamination and needlestick injury risk. This method differs from manufacturer instructions and may constitute compounding under applicable regulations. Facilities should follow internal protocols and regulatory guidance.
Supplies	**Supplies**	**Supplies**
▪ Teplizumab vial(s) ▪ 20 mL vial of 0.9% Sodium Chloride Injection ▪ PVC infusion bag with 25 mL 0.9% Sodium Chloride ▪ 30 mL empty vial ▪ 3 mL syringe ▪ 10 mL syringe ▪ 30 mL syringe ▪ Blunt fill needles ▪ Alcohol prep pads	▪ Teplizumab vial(s) ▪ Infusion bag with 0.9% Sodium Chloride Injection ▪ Sterile 50 mL (or larger) empty PVC infusion bag ▪ PVC infusion bag with 25 mL 0.9% Sodium Chloride ▪ 3 mL syringe ▪ 10 mL syringe ▪ 30 mL syringe ▪ Blunt fill needles ▪ Alcohol prep pads	▪ Teplizumab vial(s) ▪ PVC infusion bag with 50 mL 0.9% Sodium Chloride Injection ▪ 3 mL syringe ▪ 10 mL syringe ▪ 30 mL syringe ▪ Bag access spike with needleless connector ▪ Luer-to-luer transfer connector ▪ Alcohol prep pads

A. Empty 30 mL Vial and 30 mL Vial of Saline:	B. Empty 50 mL Infusion bag and 50 mL Bag of Saline:	C. Sterile 30 mL syringe
		
A. Disinfect* septa of empty 30 mL vial** and a 20 mL vial of 0.9% Sodium Chloride. **B.** Withdraw 18 mL 0.9% Sodium Chloride and slowly inject into the empty sterile vial. **C.** Discard remaining 0.9% Sodium Chloride and syringe/needle.	**A.** Disinfect the injection ports on both infusion bags. **B.** Withdraw 25 mL from 50 mL bag 0.9% Sodium Chloride into a 30 mL syringe. **C.** Change needle and transfer 18 mL of 0.9% Sodium Chloride into empty PVC infusion bag. **D.** Discard syringe with remaining 7 mL 0.9% Sodium Chloride Injection. **E.** Bag with 25 mL 0.9% Sodium Chloride remaining will contain final preparation.	**A.** Spike a 50 mL bag of 0.9% Sodium Chloride using bag spike with needleless connector. **B.** Disinfect needleless connector. **C.** Withdraw 7 mL into a 10 mL syringe; discard per policy. **D.** Disinfect needleless connector. **E.** Withdraw 18 mL into a 30 mL sterile syringe. **F.** Disconnect syringe and attach a luer-to-luer syringe transfer device. **G.** Bag with 25 mL 0.9% Sodium Chloride remaining will contain final preparation.
* "Disinfect" = vigorously scrub with antiseptic such as alcohol or CHG, and allow to completely air dry	** Using a larger-volume container provides more space for dilution and reduces the risk of contamination or spillage during preparation.	*** The technique described in this section represents a clinically accepted variation from manufacturer instructions intended to minimize the risk of microbial contamination and needlestick injury. This guidance does not constitute a recommendation to deviate from the manufacturer's labeled instructions and is provided solely for informational purposes. Clinicians should follow their facility's protocols, professional judgment, and applicable regulatory standards when preparing and administering medications.

b. Dilute teplizumab-mzwv 2 mg:

i. Use strict aseptic technique to carefully add 2 mL teplizumab to the prepared container with 18 mL of 0.9% Sodium Chloride.

1. If using the alternative preparation method- attach the syringe with 2 mL of teplizumab to the luer-to-luer transfer connector attached to the 30 mL syringe containing 18 mL of 0.9% Sodium Chloride Injection and slowly transfer teplizumab into the syringe, taking care not to create turbulence or foaming.

ii. Gently invert the diluted teplizumab to allow the solution to evenly disperse. Do not shake.

4. Final Preparation

a. Use appropriate size syringe(s) to accurately withdraw the ordered volume of diluted teplizumab from the intermediate solution containing 2 mg/20 mL (100 mcg/mL).

> Multiple syringes may be required to accurately measure certain doses (e.g., to obtain 2.3 mL teplizumab, using a 3 mL syringe to withdraw 2 mL and a 1 mL syringe to withdraw 0.3 mL).

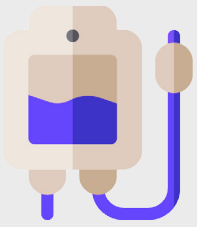
b. Disinfect the injection port of PVC infusion bag containing 25 mL 0.9% sodium chloride.

c. Slowly instill required volume of teplizumab solution.

d. Gently mix by inverting; do not shake.

e. Label the prepared solution with drug, dose, volume, date, and time of preparation.

f. Begin the infusion within 2 hours of preparation and complete within 4 hours of the start of the preparation. Discard the solution if it has not been administered within 4 hours of preparation.



Infusion Administration

1. Verify the patient's identity using two unique identifiers and confirm the correct dosage for the treatment day.

2. Administer Infusion:

a. Attach an administration set to the prepared teplizumab infusion bag.

b. Prime the infusion set.

c. Follow organizational policy to assess and disinfect the vascular access device.

d. Connect the administration set to the vascular access device.

e. Infuse over 30 minutes. A rate-control device, such as an infusion pump is recommended.

f. Monitor vital signs every 15 minutes and assess for signs of adverse reactions.

i. Watch for symptoms like fever, chills, nausea, rash, or hypotension. If present, immediately STOP the infusion and treat per orders or organizational protocol.

3. When infusion is complete, flush the administration set (at the same infusion rate) with a sufficient volume of 0.9% Sodium Chloride Injection to ensure all residual medication is delivered.

> This is a small but important operational step given the small total volume – the small residual volume in the dead space of the admin set can result in missing a significant fraction of a day's dose if not flushed.

Post-Infusion Monitoring and Care

1. Assess for manifestations of an adverse reaction, including assessment of vital signs.

2. Observation Period: Maintain vascular access and continue to monitor the patient for signs of adverse reactions for one (1) hour post-infusion.

3. Discharge Instructions: Review and provide a written copy of the post-infusion instructions with the patient and caregiver, including signs of adverse effects to monitor at home, who to contact with questions or concerns, and when to seek medical attention.

4. Follow-up Appointment: Remind the patient of their next appointment time and reinforce the importance of strict adherence to the 14-day schedule.

5. Missed Dose: If a dose is missed, administer the remaining doses on consecutive days to complete the course of treatment (provided the reason for interruption isn't a contraindication to further treatment). Do not administer 2 doses in the same day.

Appendix: Visual References

Luer-to-luer transfer connector	Bag access spike with needleless connector
	

Teplizumab Referral Checklist

- ☐ **Prescriber Details**
  - ☐ NPI number
  - ☐ Contact information
    If possible, include the most direct number to reach the prescriber quickly, if needed—such as a back line or direct clinical extension
- ☐ **Clinical Documentation to Support Medical Necessity**
  - ☐ Diagnosis of stage 2 type 1 diabetes, including:
    - ☐ Positive islet autoantibody results (at least 2 antibodies)
    - ☐ Evidence of dysglycemia (e.g., OGTT)
  - ☐ Family history of type 1 diabetes (if applicable)
  - ☐ Prior treatment plan and rationale for teplizumab
- ☐ **Baseline Laboratory Results**
  - ☐ CBC with differential
  - ☐ LFTs: AST, ALT, total bilirubin
  - ☐ Applicable screening results
    - ☐ ANA; TB; acute Epstein-Barr virus (EBV); cytomegalovirus (CMV)
- ☐ **Insurance and Authorization Documents**
  - ☐ Copy of insurance card (front and back)
  - ☐ Demographic face sheet including contact info
  - ☐ Signed prior authorization form (if applicable)
  - ☐ Any payer-specific medical necessity attestation forms
- ☐ **Signed Medication Order**
  - ☐ Teplizumab treatment order including:
    - ☐ Doses calculated for each day OR instructions for infusion center to calculate, including whether to re-weigh daily or use Day 1 weight throughout
    - ☐ Premedication instructions
    - ☐ Lab monitoring plan
    - ☐ PRN orders for managing infusion reactions
- ☐ **Signed Consent** *[if facility requires this to be obtained by prescriber]*
  - ☐ Documentation of informed consent discussion
  - ☐ Pediatric assent if applicable

NATIONAL INFUSION CENTER ASSOCIATION

Teplizumab Order Set

Name: DOB:

DIAGNOSIS

ICD-10 code | Description | ICD-10 code | Description

NURSING ORDERS

☑ Hold infusion and notify provider for:
- signs/symptoms of new or worsening **CRS:**
  - fever, nausea, fatigue, headache, myalgia, arthralgia
- signs/symptoms of active infection
- recent vaccination
  - live-attenuated vaccine within last 8 weeks
  - inactivated or mRNA vaccine within last 2 weeks
- lab results outside hold parameters below

☑ Monitor vital signs at baseline, every 15 minutes, at completion, and prior to discharge.

☑ Confirm treatment day, BSA calculation, and corresponding calculated dose prior to preparation.

☑ If signs/symptoms of infusion-related reaction develop, **STOP** infusion and treat as clinically indicated per protocol

LAB ORDERS

Lab Protocol: **STAT:** immediate processing; review before infusion **ROUTINE**: standard processing; review before *next* infusion

TEST	FREQUENCY	PRIORITY/REVIEW	HOLD PARAMETERS
☐ **AST, ALT, total bilirubin**	☐ on Day 1, 3, 5, 8, 14 ☐ other:	☐ STAT ☐ Routine	• AST or ALT greater than 2x ULN • bilirubin greater than 1.5x ULN
☐ **CBC w/diff**	☐ on Day 1, 3, 5, 8, 14 ☐ other:	☐ STAT ☐ Routine	• ANC less than 500 cells/µL • Hgb less than 10 g/dL • PLT less than 50,000/µL
☐ **Urine HCG, qualitative**	☐ on Day 1 ☐ other:	☐ STAT	• Positive result

PREMEDICATION ORDERS

Administer at least 30 minutes prior to infusion to allow for therapeutic effect.

☐ cetirizine 10 mg PO once	☐ Days 1–5 only	☐ Days 1–5; then PRN on Days 6-14	☐ Days 1-14
☐ ibuprofen 800 mg PO once	☐ Days 1–5 only	☐ Days 1–5; then PRN on Days 6-14	☐ Days 1-14
☐ acetaminophen 1000 mg PO once	☐ Days 1–5 only	☐ Days 1–5; then PRN on Days 6-14	☐ Days 1-14
☐ ondansetron 8 mg SL may sub PO if needed based on availability	☐ Days 1–5 only	☐ Days 1–5; then PRN on Days 6-14	☐ Days 1-14

MEDICATION ORDERS

Prescriber to complete at time of order:

Enter height, weight, and BSA at right. Then calculate treatment day–specific doses and enter below.

$$\sqrt{\left[\left(\frac{\text{height (cm)}}{} \times \frac{\text{weight (kg)}}{}\right) \div 3600\right]} = \frac{\text{BSA}}{}\ \text{m}^2$$

Treatment Day Weight-Based Dose	**Day 1** 65 mcg/m^2	**Day 2** 125 mcg/m^2	**Day 3** 250 mcg/m^2	**Day 4** 500 mcg/m^2	**Day 5 - 14** 1030 mcg/m^2
ORDERED DOSE					

☑ **Dilute ordered dose of teplizumab-mzwv in 25 mL 0.9% sodium chloride and administer over at least 30 minutes.**

POST-INFUSION

☑ Flush admin set with with 0.9% sodium chloride per protocol to ensure delivery of residual medication.

☑ Observe patient for 1 hour to monitor for adverse effects before discharge.

☑ Ensure patient receives and understands home care instructions, including signs to report and contact information for questions or urgent concerns

☑ Fax treatment notes to prescriber at: _____
Fax Number

Prescriber Name (print) | Signature | Date

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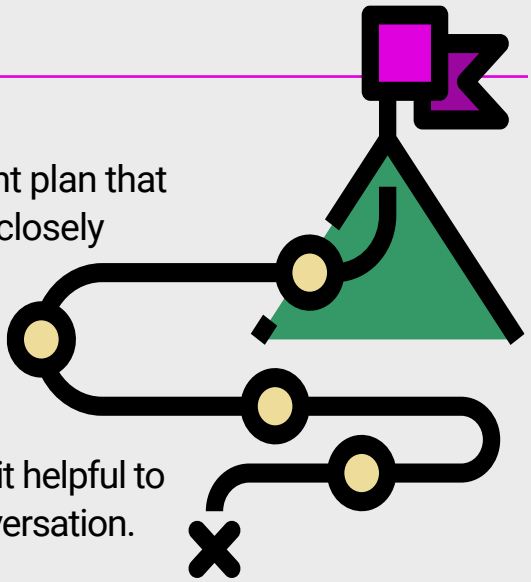
PATIENT AND CAREGIVER RESOURCES

Infusion Access Foundation

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.

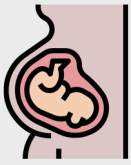
Important Safety Information

- 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

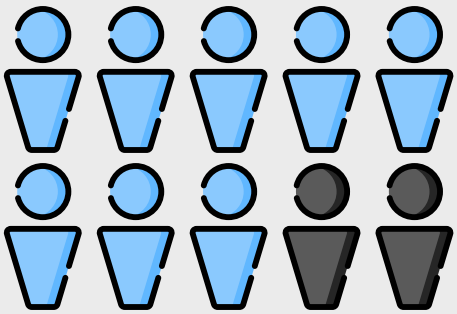
Breastfeeding

- 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.

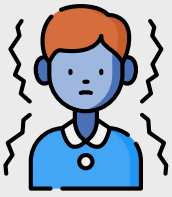
Even though a drop in white blood cells is common with teplizumab, it's usually temporary. Your healthcare provider will monitor your blood counts to keep everything on track.

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.

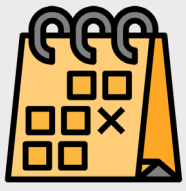
You may feel like you're coming down with something. Symptoms can include:

- 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.



Your healthcare provider may give you instructions or prescriptions to help manage these symptoms at home, such as pain relievers, antihistamines, and anti-nausea medications. For most people, these symptoms are mild and go away on their own, but it's still important to let your care team know when you're not feeling well or if anything feels worse than expected.

Infusion Access Foundation

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.

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.

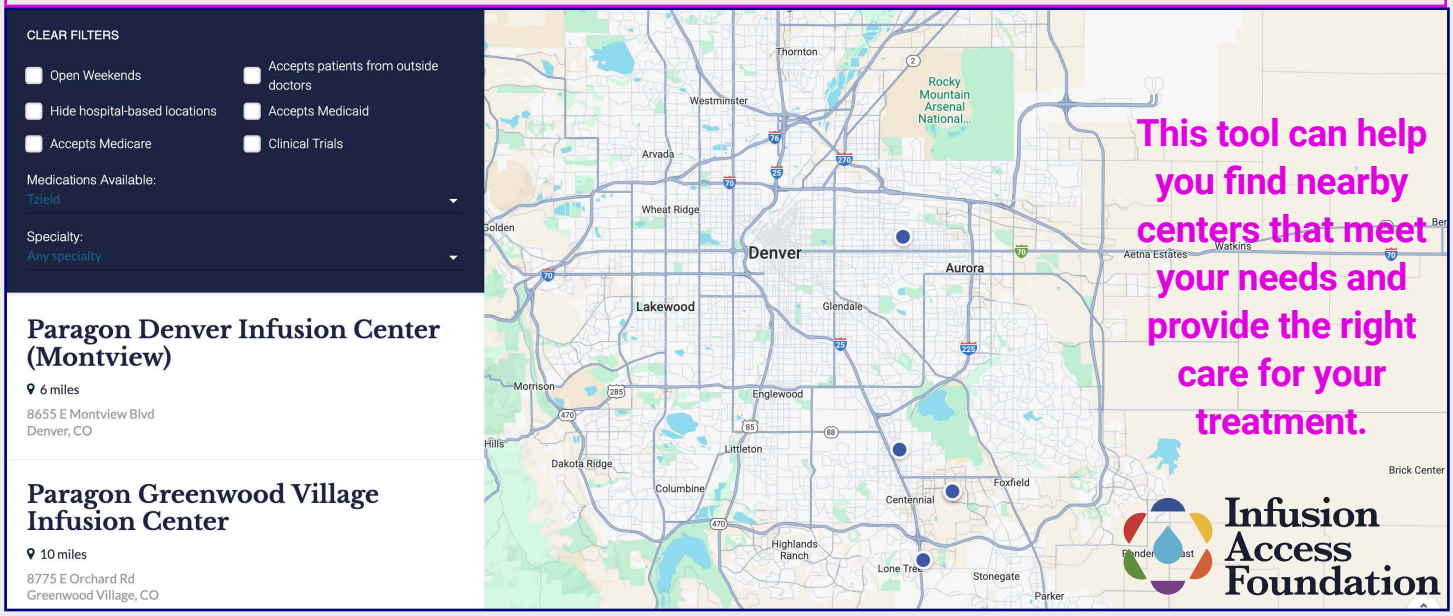
Find a Site of Care

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.

To help you find a suitable infusion center, visit the Infusion Center Locator at https://infusionaccessfoundation.org/locator.



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:

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

- **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]*

"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.

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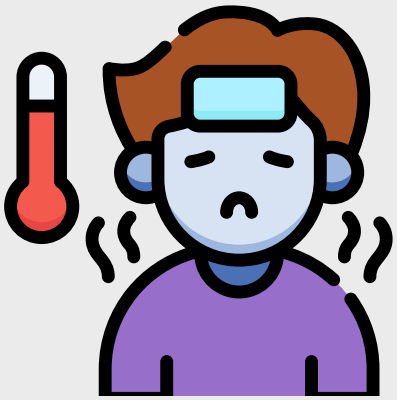
Preparing for Infusion Day

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.

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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.

Together for Treatment.

Infusion Access Foundation

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 nurse[1] 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...

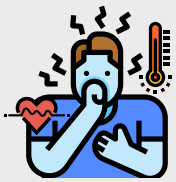
While you're getting an infusion, there isn't actually a needle in your arm! Sometimes people worry about keeping their arm completely still because they imagine a sharp needle in their vein.

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).

[1]This 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

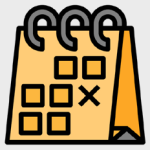


During the infusion:

- 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.

Together for Treatment.

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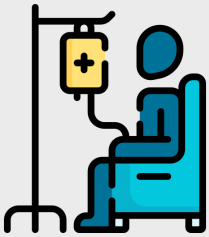
Discharge Instructions After Your *Teplizumab* Infusion

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)

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

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

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

ADDITIONAL RESOURCES

Additional Resources

Ask the Experts
https://www.asktheexperts.org/

Breakthrough T1D
https://www.breakthrought1d.org/early-detection/

DETECT-T1D Website
https://detect-t1d.com/

NICA Teplizumab Infusion Center Locator
https://locator.infusioncenter.org/medication/tzield

Pediatric Endocrine Society Statement On Considerations for the Use of Teplizumab in Clinical Practice
https://karger.com/hrp/article/doi/10.1159/000538775/906682/Pediatric-Endocrine-Society-Statement-on

Type 1 Diabetes TrialNet
https://www.trialnet.org/