

# **Navigating CD19 CAR**

## **T-cell Therapy:**

A Guide for Pediatric Patients

**Pediatric Blood and Bone Marrow  
Transplant Program**



**C.S. MOTT  
CHILDREN'S HOSPITAL**  
MICHIGAN MEDICINE

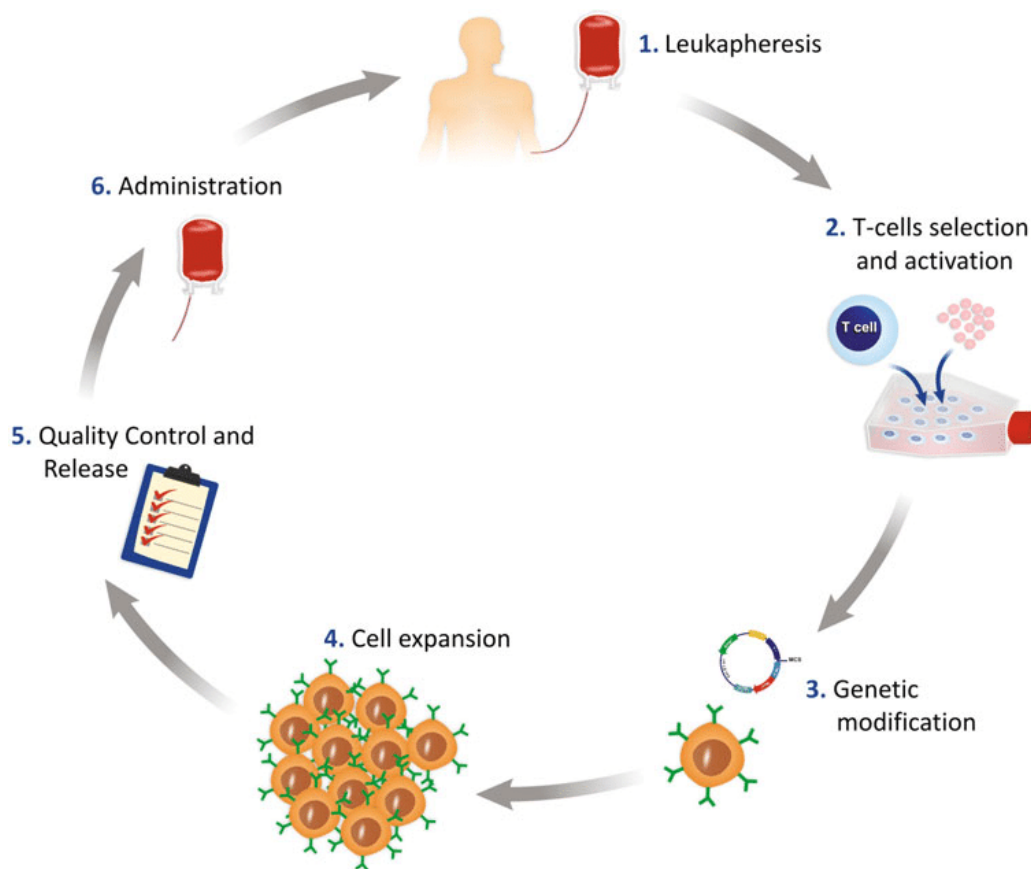
# Table of Contents:

<b>An Overview of CAR T-cell Therapy.....</b>	<b>3</b>
<b>Part 1: Conditioning.....</b>	<b>5</b>
Your conditioning plan.....	5
Side effects of conditioning.....	5
Blood count information.....	6
Blood transfusions.....	7
Central line care.....	7
<b>Part 2: The CAR T-cell Infusion.....</b>	<b>8</b>
The day of the your CAR T-cell infusion (Day 0).....	8
Side effects of the infusion.....	8
Medications to prevent infection.....	9
<b>Part 3: After Your Infusion &amp; Treatment Side Effects.....</b>	<b>11</b>
Fluids, electrolyte abnormalities, and nutrition (FEN) monitoring.....	11
Side effects during the therapy process.....	13
<b>Part 4: Discharge and Recovery.....</b>	<b>18</b>
Goals for discharge.....	18
Medications.....	18
Home health precautions.....	19
Reproductive and sexual health after therapy.....	21
BMT clinic follow-up visits.....	23
Emergency symptoms to watch for.....	23
Contact information for the BMT team.....	25

# An Overview of CAR T-cell Therapy

## What is CAR T-cell therapy?

Chimeric Antigen Receptor cell therapy, or **CAR T-cell therapy**, is a form of immunotherapy that uses your own T-cells — a part of the immune system — and changes them so that they will fight cancer. T-cells' role in the immune system is to hunt down and destroy abnormal cells, including cancer cells. However, for many different reasons, they don't always recognize or attack cancer cells. Turning them into CAR T-cells is a way to fix this issue. Once infused into your body, the CAR T-cells immediately start targeting and destroying cancer cells.



CAR T-cell therapy includes the following parts:

- **Conditioning:** a few days before your CAR T-cell infusion, when you're admitted to the hospital and receive chemotherapy to prepare your body for the treatment
- **CAR T-cell infusion:** the day of your CAR T-cell therapy infusion
- **After infusion:** the few days after your CAR T-cell therapy
- **Recovery:** your healing and wellness journey after you are discharged from the hospital

Read through this booklet to learn more about each part of CAR T-cell therapy.

# Part 1: Conditioning

## What should I expect during conditioning?

The preparation time before your CAR T-cell infusion is called **conditioning**. During this time, you may be admitted into the hospital. Conditioning involves chemotherapy, given to you for 2 main reasons:

- Killing cancer cells
- Suppressing (weakening) your immune system

## Your conditioning plan:

Fill this out with your provider.

- Day ( ): \_\_\_\_\_
- Day ( ): \_\_\_\_\_
- Day ( ): \_\_\_\_\_
- Day ( ): \_\_\_\_\_
- Day ( ): \_\_\_\_\_
- Day ( ): \_\_\_\_\_
- Day ( ): \_\_\_\_\_

## What are the side effects of conditioning?

You can expect certain side effects from each of the medicines you receive during conditioning. These will be managed with medications and other supportive care measures. Commonly expected side effects include:

- Nausea or vomiting
- Diarrhea
- Mucositis (mouth sores, throat pain, heart burn, stomach pain)
- Hair loss
- Bleeding

These side effects can last throughout the treatment course, but they are usually not permanent.

### **What is a complete blood count (CBC)?**

The **complete blood count (CBC)** is a test that measures your blood cell levels.

This includes the following counts:

- White blood cells (WBC)
  - Absolute neutrophil count (ANC)
  - Absolute lymphocyte count (ALC)
  - Blast cells
- Red blood cells
  - Hemoglobin
  - Hematocrit
- Platelets

We will look at your counts for changes during conditioning, and later to see how your body is responding to your treatment.

### **What happens to my white blood cell levels during conditioning?**

We monitor your labs (the results of your blood draws) closely and expect that your ANC and ALC levels will decrease (often as low as 0) during and after conditioning.

- After treatment, these counts will hit a low point called the **nadir**. At the nadir, you are at high risk of developing an infection. We will give you medications to try to prevent infection.
- The nadir is also the time where you may lose your hair and feel general weakness.
- To reduce the risk of infection, you will not be allowed to leave the unit while your counts are at this point.

- After your infusion, it is likely that you will be **neutropenic** (have low white blood cell counts) for a period of time as the CAR T-cells do their job.

### **Will I need blood transfusions?**

In addition to your ANC declining, you will also notice a decline in your hemoglobin and platelet numbers. You will likely need a transfusion of blood products, including packed red blood cells (pRBC) and platelets, until your body is able to produce them on its own. You may experience some bleeding (nose bleeds, mouth bleeding) at this time.

- You may need a blood transfusion if your platelet count is less than \_\_\_\_\_ or your hemoglobin is less than \_\_\_\_\_.
- If you've had a reaction to blood transfusions in the past, you may get medication such as Tylenol®, Benadryl®, or steroids before the transfusion to try to prevent that reaction.

### **What do I need to know about central line care?**

You will have a **central line** (a long flexible tube that enters your body through a vein, which helps to give you treatments) placed when you're admitted to the hospital. Most patients will go home with their central line in place, and it will stay in for months. We encourage you to become actively involved in the care of this line, starting from your admission (check-in) to the hospital, so that you have time to learn and feel comfortable caring for this line at discharge (when you leave the hospital). Care of your central line includes flushing the line, cap changes, and dressing changes. Your nurse will help teach you and oversee your care.

## Part 2: The CAR T-cell Infusion

### What can I expect on the day of my CAR T-cell infusion (Day 0)?

The day you receive your CAR T-cell infusion is called “Day 0.”

Treatment date: \_\_\_\_\_

### What should I expect during the infusion?

- We will deliver CAR T-cells to your room in a syringe. They will be thawed at your bedside.
- You may receive medications and IV fluids to reduce your side effects before you get your infusion.
- Your nurse will infuse (give you) your cells through your central line, similar to the way you receive blood or IV medications.
  - If your stem cells are frozen, you may notice a smell during the infusion. Some people describe the smell as garlic, tomato juice, or creamed corn. This is normal, and it is from the preservative used when the cells are collected and frozen.
- The entire process from start to finish will take a few minutes.
- A doctor, nurse practitioner, or physician assistant will be present to monitor you (check on you) throughout the process.
  - We will monitor your vital signs (heart rate, etc.) more often during the infusion.

### What are the side effects of the infusion?

Many patients have no issues with their infusion. However, some of the most common side effects include:

- High blood pressure
- Nausea or vomiting



- Fever
- Hives (small itchy bumps on your skin)
- Allergic reaction (rash, difficulty breathing, face swelling)

Many of these side effects typically go away when the infusion is over. However, we may need to do other things to help your side effects, such as giving you medications and longer monitoring and care.

**What medications will I take to prevent infections?**

During your admission and after your discharge, you will be taking several different medications to reduce your risk of viral, bacterial, and fungal infections.

<b>Medication type: Anti-bacterial</b>		
<b>Brand names:</b>	<b>When you start taking it:</b>	<b>When you stop taking it:</b>
Levaquin® Vantin®	Day +1 (the day after your infusion)	<ul style="list-style-type: none"> <li>• If you develop a fever, we will usually have you stop taking this and give you a stronger IV medication.</li> <li>• Once your ANC is greater than 500 K/uL</li> </ul>

<b>Medication type: Anti-viral</b>		
<b>Brand names:</b>	<b>When you start taking it:</b>	<b>When you stop taking it:</b>
Acyclovir®	Day 0	<ul style="list-style-type: none"> <li>• 1 year</li> </ul>

<b>Medication type: Anti-fungal</b>		
<b>Brand names:</b>	<b>When you start taking it:</b>	<b>When you stop taking it:</b>
Fluconazole® Micafungin®	On admission	<ul style="list-style-type: none"> <li>• Until your ANC is greater than 1000 K/uL and you are in remission</li> </ul>

<b>Medication type: Pneumocystis jiroveci pneumonia (PJP) treatment</b>		
<b>Brand names:</b>	<b>When you start taking it:</b>	<b>When you stop taking it:</b>
Pentamidine® Bactrim®	Day -1 (the day before your infusion)	<ul style="list-style-type: none"> <li>6 months after your infusion and when your CD4 (a blood count that tells us about your immune system functioning) is greater than 300 cells/mm</li> </ul>

<b>Medication type: Intravenous immunoglobulin (IVIG)</b>		
This medication is a boost of antibodies that can kill bacteria, fungi, or viruses.		
<b>Brand names:</b>	<b>When you start taking it:</b>	<b>When you stop taking it:</b>
---	You will be given this as needed based on your lab values.	

## Part 3: After Your Infusion & Treatment Side Effects

### What can I expect in the days after my infusion?

#### Fluids, electrolyte imbalance, and nutrition (FEN) monitoring

We will monitor you for the following:

- Fluids
- Electrolyte abnormalities
- Nutrition

#### Fluids:

You will get fluids through an IV:

- As needed during your hospital stay (including if you are not able to drink enough fluid)
- Continuously before, and for 1 day after, your CAR T-cell infusion

Your daily fluid goal is: \_\_\_\_\_ mL/day

- We monitor your weight once or twice a day to check for **fluid overload** (too much fluid in your body).
- We may give you medication such as Lasix<sup>®</sup> to help your body remove extra fluid.

#### Electrolyte abnormalities:

If you have an **electrolyte abnormality**, this means that one or more of the lab values we measure in the blood (such as magnesium, potassium, phosphorus, or sodium) is higher or lower than normal.

- There are many causes of this, including eating less, diarrhea, medications, and IV fluids.
- The most common abnormalities are high or low potassium.

Treatment for any electrolyte abnormality may include:

- Fixing the cause of the abnormality
- Oral (by mouth) or IV electrolyte replacement
- Adjusting your medications

**Nutrition:**

You may feel less hungry (you “lose your appetite”) and eat less after your infusion. The main causes are nausea, taste bud changes, and oral (mouth) pain. Getting good nutrition is important for your healing and overall health!

A dietitian will teach you about a specific BMT (blood and marrow transplant) diet. Treatment for your nutritional needs may also include:

- Feeding through the gastrointestinal (GI) tract (stomach and intestines), called **enteral nutrition**
  - You may take supplements by mouth to get more calories and protein. There are many types and flavors of supplements.
  - You may have **tube feeds**, where you’re given medication and liquid nutrition through a small tube placed through the nose into the stomach or small intestine.
- Feeding through an IV, called **parenteral nutrition**
  - You may have **total parenteral nutrition (TPN)**, where all of the protein, calories, vitamins, and minerals you need are given to you through a vein. This type of feeding does not use your digestive system. It can irritate your liver and increases your risk of infection.

Your daily caloric goal is: \_\_\_\_\_kCal/day

You will get these medications to help prevent FEN-related issues:

- Glutasolve® (an amino acid which promotes healing of the GI tract)

- Liver/biliary protection: Actigall®
- Stomach ulcer prevention: Zantac®, Pepcid®, or Prilosec®
- Vitamin D deficiency: cholecalciferol

## **What side effects could I have during my CAR T-cell therapy?**

### **Mucositis**

**Mucositis** is a common side effect of chemotherapy. It is pain and swelling (inflammation) of the body's mucous membranes. A **mucous membrane** is the soft layer of tissue lining parts of your body, particularly the digestive system from your mouth to your bottom. Mucositis can cause your skin or the surface of soft tissue to break down.

### **What are the symptoms?**

- Mouth sores or changes to the inside of your mouth
- Change in taste buds and loss of appetite
- Pain or discomfort in your mouth, esophagus (the tube that food and liquid moves through from your throat to your stomach), or stomach
- Nausea, vomiting, or diarrhea
- Drooling thick or thin fluid
- Hoarse (rough or harsh) voice

### **How can I reduce these symptoms?**

- Take good care of your mouth (brush 4 times a day, use lip balm)
- Take amino acid supplements (like Glutasolve®)

### **What is the treatment?**

- Pain medication: you'll usually start taking pain medication for mucositis as a pill, but you may also need IV pain medication.

- Magic mouthwash: this is a mouth rinse that we will give you during your hospital stay.

### **When will I start to heal?**

The sores and your mucositis will get better as your counts start to rise.

### **Gastrointestinal (GI) complications**

#### **Nausea and vomiting:**

- This is the most common side effect of chemotherapy.
- To prevent or treat nausea and vomiting, some medications will be given to you on a set schedule while others may be given to you as needed when you're feeling sick.
  - Commonly used medications include Zofran<sup>®</sup>, Kytril<sup>®</sup>, Zyprexa<sup>®</sup>, Ativan<sup>®</sup>, and Phenergan<sup>®</sup>.
  - Your medication plan: \_\_\_\_\_

#### **Diarrhea:**

- Diarrhea is usually caused by mucositis, although it may also be caused by a virus or bacteria.
- Diarrhea is treated with hydration (IV fluids) and giving time for the GI tract to heal. If you have infectious diarrhea, you may need antibiotics.

#### **Constipation:**

- Constipation (not being able to have bowel movements, or having hard bowel movements) is usually caused by not eating or by side effects of pain medication.
- Constipation can be treated by eating and drinking (when possible) to keep things moving in your GI tract. You may also take medications to help with bowel movements like Senna<sup>®</sup>, Colace<sup>®</sup>, Miralax<sup>®</sup>, or Lactulose<sup>®</sup>.

### **Cytokine release syndrome (CRS)**

CAR T-cells can cause a large release of substances called **cytokines** from the cells in your body. This can trigger an inflammatory condition known as **cytokine release syndrome (CRS)**.

### **What are the symptoms?**

Symptoms of CRS can range from mild to severe. Common symptoms include:

- A temperature of 100.4° F (38° C) or higher
- Flu-like symptoms, such as muscle aches, headaches, or chills
- Nausea or vomiting
- Diarrhea
- Feeling dizzy or lightheaded

More severe symptoms include:

- Confusion
- Difficulty breathing
- Low blood pressure
- Trouble speaking
- Seizures

### **How can I reduce these symptoms?**

These side effects are usually managed with supportive care and medications. This may require close observation in the Pediatric Intensive Care Unit (PICU). If the symptoms become severe, we will give you a medication called tocilizumab to calm this response.

## **Neurotoxicity**

A neurological effect, known as **neurotoxicity**, can occur with CAR T-cell therapy. Neurotoxicity is when your normal brain and nervous system activity is changed or damaged after exposure to a substance.

### **What are the symptoms?**

Neurotoxicity symptoms range from mild to severe. Symptoms include:

- Headache
- Confusion or delirium (having a hard time focusing your attention and awareness, not being able to think or remember clearly)
- Hallucinations (sensing things that aren't real)
- Difficulty speaking (aphasia)
- Involuntary muscle twitching
- Unresponsiveness
- Seizures

### **What is the treatment?**

Neurotoxicity has been reversible in most cases, and the symptoms usually go away over several days without intervention or long-term effects.

### **Fever and neutropenia (low white blood cell count)**

While your white blood cell counts are low, you are very likely to get a fever. This might be caused by an infection, inflammation, or cytokine release syndrome (CRS).

- Inflammation can be caused by cell irritation from chemotherapy.
- The most common sources of infection are from your central line, your GI tract, or your respiratory system (your nose, mouth, throat, windpipe, and lungs).



### **What are the symptoms?**

While you have a fever, some symptoms you might experience are:

- Tiredness
- Elevated (faster) heart rate
- Blood pressure changes
- Changes in your breathing
- Chills and shaking

If you have an infection, you may also have symptoms specific to infection site (like stomach pain, pain with urination, diarrhea, runny nose, cough, etc.).

### **What testing will I need?**

If you have a fever or neutropenia, we will need to do these tests to rule out an infection:

- Blood cultures from all of your lines (if you have a fever, we will access your port)
- Possible viral labs
- Possible fungal labs
- Possible x-rays or CT scans
- Respiratory (nose) swabs
- Stool (poop) cultures
- Urine (pee) samples

### **What is the treatment?**

We will need start treating you immediately, just in case the cause of your fever or neutropenia is an infection.

- As a safety measure, we may need to change the antibiotics and antifungals that you were on.
- We will continue to treat you as if you have an infection until we determine that you don't have an infection.

## Part 4: Discharge and Recovery

### What are my goals for discharge?

Before you are cleared to leave the hospital (called **discharge**), we expect that:

- It has been 10 days since your CAR T-cell infusion
- You need blood product transfusions 2 days or less per week
- You have not had a fever for more than 24 hours
- You have no active infections
- You have limited nausea, vomiting, or diarrhea
- You are able to take medications by mouth
- You're meeting your goals for calories and fluid intake
- You are able to move around and perform daily care activities (like bathing, taking medications, etc.)
- Your discharge medications have been delivered to your bedside so we can go over them with you
- Your central line supplies have been delivered to your bedside
- Your caregiver has shown the hospital staff that they're able to care for your lines and medications
- Other: \_\_\_\_\_

### What medications will I take at home?

- You will receive your medications from the Taubman Pharmacy before discharge. We will check these at your bedside to make sure you have the right medications, and we will teach you about them. You are expected to know what these medications are, as well as when and why you are taking them.
- After discharge, you must bring these medications to the clinic with you for your follow-up appointments. Some medications (such as posaconazole) require lab monitoring to check and adjust your doses. **On**

**clinic days, you will not take this medication until after your labs have been drawn.**

- You may go home with IV medications or IV fluids. You should take these around the same time each day.
  - You will be responsible for completing central line care and weekly dressing changes at home. You will learn and practice central line care during your hospital stay. Skilled nursing staff will help you with this process at home as well. Our case manager will work with you to set up home care before discharge.

### **What do I need to do to prevent sickness and stay healthy at home?**

You must take the following **precautions** (actions to help you avoid getting sick) until you are cleared by your BMT doctor.

#### **Personal hygiene (cleanliness)**

- Shower or bathe every day. All your family members and people staying around you should also shower or bathe daily.
- Avoid direct sunlight. Your skin will be more sensitive after your therapy. Protect your skin with a sunscreen that has an SPF of at least 30. Reapply (put more on) often. Cover your skin with cotton clothing and a protective hat.
- Don't get any new tattoos or piercings.
- Avoid wearing contact lenses. Wear eyeglasses instead to prevent infection.

#### **Masking**

- Wear a facemask when you're coming to the clinic or hospital, or when you'll be around large crowds of people.

### **Being around other people**

- Avoid being around anyone who is sick. Ask your guests to take their temperatures before coming over and make sure they have not had colds, rashes, vomiting, or diarrhea.
- Avoid crowds of people.
- Try to limit your time around children younger than 12 who are not part of your immediate family.
- Call your doctor immediately if you, or any other friend or family member around you, is exposed to chickenpox, shingles, measles, German measles (rubella), or any other contagious (easy to spread) disease.

### **Pets**

- **Do not get any new pets.**
- Don't clean up after your pets. This includes changing a litter box or picking up poop.
- Wash your hands after any contact with pets.
- Do not touch any birds or farm animals.
- Do not keep any reptiles (lizards, snakes) or amphibians (frogs, toads) in your home.

### **Home safety and cleanliness**

- Don't play in the dirt or leaves. This includes avoiding gardening and caring for plants. Do not get a living pine tree for the holidays.
- Don't do any chores where you'd come into contact with dust.
- Do not use a bedside humidifier.
- Do not have your carpets cleaned.
- Avoid lung irritants such as smoking, secondhand smoke (being around other people who are smoking), and aerosols (like spray paint).

### **School and work**

- You can't go back to school or work until your doctor says it's okay.
- You may continue your education at home using printed or computer material through a virtual program.

### **Substance use (including alcohol, nicotine, inhaled marijuana, vaping and illicit drug use)**

- **To keep you safe, you should not use any of these substances after your therapy unless you've talked with your doctor about it.** There are possible drug interactions (harmful or unsafe drug combinations) and risks of organ dysfunction with many of these substances.
- Smoking and vaping (tobacco or marijuana) can lead to lung injury, fungal infection, and secondary cancer risk.
- Drinking alcohol can harm your liver and interact with your medications.

### **Other activities**

- Ask your doctor when you can travel and drive. You cannot drive for at least 8 weeks.
- **Do not swim if your central line is still in place.** Once your central line is removed, you can swim in a private pool that isn't crowded if you aren't neutropenic. Make sure that the pool is chlorinated. You cannot swim in lakes, rivers, or crowded pools until your immune system has recovered.

### **What do I need to know about reproductive and sexual health after my therapy?**

Because of the physical changes to your body after your CAR T-cell therapy, you may be affected physically and emotionally with your sexual activity. It is normal to feel more self-conscious or nervous. Changes to your sexual health that you may experience after therapy include:

- Trouble having an orgasm
- Trouble keeping an erection
- Vaginal dryness, painful sex, or increased vaginal bleeding during menstruation (your period) or during sex

### **Will I be able to have children after CAR T-cell therapy?**

Your **fertility** (your ability to become pregnant or make someone else pregnant) may be decreased after your therapy. However, **it may still be possible to have children**. There are serious risks if you become pregnant, as it may require changes to your therapy plan which can have an effect on your health and therapy outcome. Because of your therapy, birth defects (where a baby's body develops differently than normal) are also possible.

### **How can I have sex safely?**

There will be times when you'll need to avoid sexual activity, including when your blood counts are low. This includes vaginal, oral, and anal sex, or inserting fingers, vibrators, or other sex toys into your vagina or anus. This is to prevent bleeding or major infections. Until your doctor tells you that your blood counts and immune system have recovered, follow these precautions:

- Avoid sexual activity when your ANC is under 1,000.
- Avoid sexual activity when your platelet count is under 50,000.
- Use condoms each time you have vaginal, oral, or anal sex.
- If using lubricant, use a water-based lubricant (like K-Y Jelly). Using other products can increase your risk of infection.
- Don't do any sexual activity where your mouth could come into contact with feces (poop).
- If you or your partner has a sexually transmitted infection (STI), or if you think you might have an STI, avoid sex that involves contact with mucous membranes (including the vagina, mouth, or anus).

- Hugging, cuddling, gentle touching, and kissing are other ways you can be intimate with your partner during this time.
  - Avoid kissing if you have mouth sores or open wounds in your mouth, or if your partner has mouth sores.

Talk with your healthcare provider if:

- You have vaginal dryness or tightness that makes sexual activity painful
- You have difficulty getting or keeping an erection
- You have any other questions or concerns

### **What should I expect for my follow-up visits in the BMT clinic after discharge?**

After discharge, if you don't have any complications requiring closer follow-up, you will be seen in the BMT clinic at least weekly for 8 weeks.

- You must stay in the Ann Arbor area, within 100 miles of the University of Michigan Medical Center, for the first 8 weeks after your infusion.
- Your first visit will take at least 1 hour.
- You may have an infusion appointment scheduled in case you need blood or platelets.
- Your lab appointments will be scheduled before your clinic appointment.

### **What should I watch for, and when should I call 911 or go to the emergency room (ER)?**

Call 911 immediately if:

- You or your child is having **trouble breathing**
- You or your child is **not responsive**
- You or your child has any other **issues that may be life-threatening**

Call the clinic and go to Mott Emergency Department, or go to your local ER (if you live more than 30 minutes away from the University of Michigan), if you notice these symptoms:

- **Fever:** We have given you a thermometer. You do not need to routinely check your temperature unless you are concerned about fever. If you need to check your temperature, do so orally (under the tongue). Rectal temperatures are not recommended for children with cancer. It's a good idea to keep a bag packed at home, just in case, as a fever usually means you will need to check into the hospital. **Call the clinic and go to the ER if your thermometer has these readings:**
  - 2 temperature readings (done one hour apart) of 100.4 °F (38 °C) or higher
  - 1 temperature reading of 100.9 °F (38.3 °C) or higher
  - Any temperature reading above 98.6 °F (37 °C) with concerning symptoms such as cough, congestion, behavior changes, etc.
- **Bleeding:** This includes nosebleeds that last longer than 10 minutes, red or black bowel movements, red or dark brown vomiting, red urine, or an increase in bruising.
- **Cognitive symptoms:** This may include extreme sleepiness or drowsiness, changes in mental status or behavior, vision changes (such as double or blurred vision), or increased pain or headaches that last several hours or are not controlled by prescribed pain medication.
- **GI symptoms:** This includes constipation or vomiting that is not helped with prescribed medications, diarrhea or pain with bowel movements, pain with urination, not being able to eat or drink, or not being able to take oral (by mouth) medications.
- **Central line problems:** This may include any pain, redness, drainage (leaking fluid) or swollen areas around central lines or port sites, a break, crack, or tear in the central line, or issues with flushing or leaking from your catheter.



## What is the contact information for my BMT team?

If you have any concerns or any of the symptoms listed above, please contact your BMT team:

- Monday through Friday 8:00 AM – 5:00 PM: Call the BMT clinic and nurse line at (734) 936-9814
- After clinic hours and on weekends: Call (734) 936-9814 and ask for the BMT provider on-call

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