

# Cancer Cellular Therapy (CCT) Guidebook



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# Cancer Cellular Therapy (CCT) Guidebook

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## Section One—Introduction

### Cancer Cellular Therapy (CCT) Guidebook

The goals of this guidebook are to:

- prepare you for your cellular therapy and what to expect before and after infusion
- serve as a resource for you and your caregiver(s)
- help you understand your treatment
- outline ways to reduce the risk of cancer cellular therapy related complications

While we have attempted to make this guidebook comprehensive, it does not cover all aspects of your care. Always consult your healthcare team regarding your specific situation.

#### Your CCT Team

It takes a large group of health care professionals to help you and your family through the cancer cellular therapy processes. The CCT team works closely with Stanford’s Division of Blood and Marrow Transplantation (BMT) as well as your disease specific oncologist. This clinical team meets regularly to work together to take care of you. You and your family are **key** members of this team. The table below lists some of the members of your CCT team.

Health Care Professionals	Responsibilities
Attending Physician	<ul style="list-style-type: none"><li>• provide initial consult</li><li>• provide medical care before your cellular infusion, during your hospitalization and until return to your referring physician.</li><li>• provide education and support as you go through cellular therapy</li><li>• teach and educate physicians in training</li><li>• conduct research to improve outcomes of cellular therapies</li><li>• communicate with your referring physician while you’re under our care</li></ul>

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<p>Nurse Coordinators and Clinical Research Coordinators</p>	<ul style="list-style-type: none"> <li>• coordinate the necessary procedures(s) throughout your cellular therapy</li> <li>• provide education about your treatment and symptom management</li> <li>• schedule your appointment to review and sign the consent form(s) with a CCT physician</li> <li>• help make arrangements for your discharge from the hospital</li> </ul>
<p>Nurse Practitioners and Physician Assistants</p>	<ul style="list-style-type: none"> <li>• take a history and perform physical exams</li> <li>• prescribe medications</li> <li>• order tests and evaluate the results</li> <li>• evaluate and treat your medical problems</li> <li>• perform certain procedures such as infusing cells, taking biopsies of the bone marrow and skin and removing the central venous catheter</li> <li>• provide education about your treatment plan and symptom management</li> <li>• provide emotional support for you and your family</li> </ul>
<p>Nurses</p>	<ul style="list-style-type: none"> <li>• provide education about your treatment plan including symptom management</li> <li>• administer chemotherapy, antibiotics, transfusions products as requested by your physician</li> <li>• make frequent assessments to detect changes in your health</li> <li>• provide supportive care to minimize and manage the side effects of treatment</li> </ul>
<p>Social Workers</p>	<ul style="list-style-type: none"> <li>• provide education about your treatment plan and follow-up care</li> <li>• provide emotional support to you and your family to help you deal with the stress of the cellular therapy</li> <li>• assist with housing arrangements</li> <li>• assist with work related issues, disability and leave programs</li> <li>• assist in the completion of an advanced health care directive</li> </ul>

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## Who to call if you have a question?

(a list of staff phone numbers is found on page 8)

### Call 911 for any Medical Emergency

Call your clinical research coordinator and Nurse coordinator for all scheduling and procedural questions.

Call the attending physician at ☎ (650) 723-0822

- questions or concerns about your cellular therapy
- to obtain test results and treatment notes please use Stanford's My Health on-line portal; to sign up please visit <https://myhealth.stanfordhealthcare.org/>

Call your social worker

- questions about disability, leave programs
- if you need a letter for your employer
- caregiver information
- assistance with housing

Call a financial coordinator

- concerns about your insurance coverage
- authorization for your cellular therapy

Call Apheresis Unit at ☎ (650) 725-4656

- questions about your apheresis schedule or the apheresis procedure

Call Infusion Treatment Area (ITA) at ☎ (650) 725-1860 or E1 Inpatient unit at ☎ (650) 725-7121

- questions about your chemotherapy and inpatient or outpatient care

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## What Medical Providers Takes Care of You?

At your initial consult with the CCT program, you will meet one of the physicians from the Cellular Therapy/Blood and Marrow Transplant (BMT) team. This attending physician will be your primary physician while you are undergoing cellular therapy. However, your primary CCT/BMT physician will not take care of you throughout your entire cellular therapy process. Attending physicians care for patients while hospitalized or while receiving care in the Cancer Center on a rotating monthly schedule. Your care will always be under the direction of an attending physician, but it may not be your primary CCT/BMT physician.

All of the CCT/BMT attending physicians have received specialized training in cellular therapy and bone marrow transplantation, and will be assisted by fellows, residents or Advanced Practice Providers. Fellows are medical doctors who have completed residency and are specializing in a field of medicine. Residents are medical doctors with one to four years of experience. Advanced Practice Providers (APPs) are either physician’s assistants or nurse practitioners with advanced degrees and are trained specifically in CCT and BMT.

## Where is Care Provided?

### CCT/BMT Clinic—F

- located on the first floor of the Cancer Center
- clinic hours are Monday thru Friday 8:30 am to 5:00 pm
- clinic phone number is ☎(650) 498-6000

### Infusion Treatment Area (ITA)

- located on the second floor of the Cancer Center
- ITA hours are:
  - Monday to Friday 7:00 am to 9:00 pm daily
  - Saturdays 7:00 am to 7:00 pm
  - Sundays 8:00 am to 7:00 pm
- ITA phone number is ☎(650) 725-1860

### CCT/BMT Inpatient Service

- located in the main hospital (E1) (24 hours/7days)
- CCT/BMT Inpatient Service phone number is ☎(650) 725-7121

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## Directions, Parking and Traffic

As of November 2, 2012, Stanford began construction for the new Stanford Hospital resulting in frequent changes in traffic patterns, directions and parking. For the most up to date information on directions, parking and traffic call the Cancer Center at 📞 (650) 498-6000.

Guest Services staff are available 24 hours a day to answer questions about your visit to Stanford. Call 📞(650) 498-3333.

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## Phone Numbers

Staff	Phone Number
<b>Clinical Research Coordinators</b> <ul style="list-style-type: none"> <li>• Juliana Craig</li> <li>• Matthew Abramian</li> </ul>	(650) 726-0912 (650) 726-0912
<b>Patient Care Managers</b> Inpatient <ul style="list-style-type: none"> <li>• Trisha Jenkins, RN, MPH</li> </ul> Infusion Treatment Area (Cancer Center) <ul style="list-style-type: none"> <li>• Torey Benoit, RN, BSN</li> </ul>	E1 Inpatient Unit  Infusion Treatment Area (ITA)
<b>Social Workers</b> <ul style="list-style-type: none"> <li>• Carrie Kowieski, MSW</li> <li>• Ana Stafford, LCSW</li> <li>• Cecelia Ellington, MSW</li> </ul>	(650) 817-5462 (650) 521-3439 (650) 7145489
<b>Dietitians</b> <ul style="list-style-type: none"> <li>• Tara Coghlin-Dickson, MS, RD, CSSD</li> <li>• - Raymond Palko RD</li> </ul>	(650) 497-3903

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## Section 2—Treatment Plan

### 2.1 Cancer Cellular Therapy Regimen

What follows is a general description of cancer cellular therapies. The consent form will provide more detail on your specific type of cell therapy

The steps of cancer cellular therapy are:

- Collection and reengineering of your immune cells (Apheresis)
- Administration of the lymphodepletion chemotherapy; this ensures a proper environment for the cells (Preparative Regimen)
- Infusion of cells
- Post-infusion recovery period (Recovery)

#### Apheresis

The cells are collected using a machine that separates the blood. Apheresis involves removing a small amount of blood through one side of your catheter (or a needle in an arm vein). The blood is spun through a machine that will collect white blood cells and return the remainder of the blood through the other side of your catheter (or a second needle in the vein of your other arm). This process takes about four hours. After the cells are collected, they are taken to the Cellular Therapy Facility or a specific laboratory for processing and modification.

#### Preparative Regimen

Once the cells have been processed and modified, you will receive the preparative regimen. The preparative regimen consists of a combination of chemotherapy drugs. The purpose of the preparative regimen is to prepare your immune system for the cellular therapy treatment. The preparative regimen typically takes up to 4 days to complete and may be given in the outpatient Cancer Center Infusion Treatment Area (ITA).

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## Cell Infusion Day

The cells are infused through your catheter one to two days after you complete the preparative regimen. During the following 1-4 weeks, you will be observed closely either on the CCT/BMT inpatient unit or in the Infusion Treatment Area. The objective during this period is to promptly identify and treat any side effects that may result from your cellular therapy. Specifically, we will be monitoring you for low blood counts, signs of fever, low blood pressure, fatigue, confusion and any other toxicities.

## Recovery

We anticipate CCT patients will be managed in hospital for a minimum of 7-9 days and are required to live “locally” for 28 days after CAR-T infusion so patients can receive immediate care at Stanford if problems arise. It is important that you are never further than 1-2 hours from Stanford Hospital during the 28 day stay. Approximately 28 days following the Cancer Cellular Therapy, your primary CCT physician will determine if your care can be transferred back to your referring oncologist. Your long term care will still include periodic checkups with your CCT physician.

Recovery from a Cellular Therapy can take up to several months or more. Your energy may remain low for a longer period of time. It is not unusual to need rest periods (naps) for up to several months after Cellular Therapy. The best strategy for regaining your energy is to walk every day.

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## Section 3—Preparing for Cellular Therapy

### Pre-Cancer Cellular Therapy Checklist

- Read the CCT Guidebook
- Review the treatment calendar with your care clinical research coordinator
- Meet with your social worker to discuss housing, disability and caregiver needs
- Identify a caregiver(s)

You will need an adult to act as your caregiver after discharge 24 hours a day, 7 days a week until you are 28 days from your cell infusion day.

- Meet with your oncologist and the CCT team to review and sign your consent form(s)
- Practice drinking 3 quarts of fluid every day
- Avoid steroids

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## Reviewing Your Treatment Plan

At your first visit with the CCT, the attending physician will outline a treatment plan based on your history, physical health and prior therapies. Your treatment plan will then be presented to the rest of the CCT team. The entire CCT team will then consider the treatment plan selected for you and discuss if this is the **BEST** treatment plan we can offer. In some cases, this means that your treatment plan may change from what was initially presented to you. We recognize that a change in plans can be stressful, but believe that you will benefit from having the expertise of the entire CCT team reviewing your treatment plan. Other reasons for a change in the treatment plan include results of eligibility testing, a change in the status of your disease, and new information about treatment outcomes.

## Review Your Insurance Coverage

Once your treatment plan is scheduled, one of the financial coordinators will request authorization for coverage from your insurance company. Certain pre treatment diagnostic studies are completed and submitted to the insurance company for review prior to treatment.

Review your Insurance Coverage:

- confirm the amount of your policy deductible (s)
- know your co-payments, your out of pocket maximum, your policy maximum
- confirm that return visits to Stanford for follow up are covered and authorized
- find out if there is coverage for housing while you stay at Stanford
- determine if there is any coverage for transportation
- know your prescription drug coverage, prescription co-pays and what pharmacies you can use

Insurance coverage for clinical trials:

- Clinical trials almost always include standard-of-care services that are the responsibility of the patient and/or their insurance company. In most cases, only direct research costs (non-FDA-approved medications, cellular therapy products, and tests done only for research) may be covered by the trial itself. Ask the trial Research Coordinator if you'd like a list of specific services covered by the trial.
- Check with your insurance to confirm that your plan covers the routine standard-of-care costs of a clinical trial. The Affordable Care Act Clinical Trial coverage

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rules require some insurance plans to cover these services, but not all plans are governed by those rules.

For assistance regarding insurance benefits & authorization, please contact a BMT Financial Coordinator.

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## Section 4—Social Services

### Your Social Worker

You will work with one of the social workers in the CCT/BMT Program throughout your Cellular Therapy regimen.

- Carrie Kowieski, MSW
- Ana Stafford, LCSW
- Cecelia Ellington, MSW

Your social worker will complete an evaluation, reviewing your:

- understanding and adjustment to your illness
- support system
- caregiver plans
- work, financial and disability issues
- ability to follow the treatment plan
- family support and how your family is coping

Your social worker will help you complete:

- an advanced health care directive
- housing arrangements
- disability forms

It is always helpful and encouraged to bring your caregiver(s) with you when you meet with the social worker.

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## SAFE ZONE

Due to the potential health risks involved and special needs you will need during your cancer cell therapy, we require that you live within a designated SAFE ZONE from the time you begin your preparative regimen until the CCT team determines it is safe for you to leave (minimum of 28 days). A location is considered to be in the SAFE ZONE if it is less than a one to two hours drive to the Stanford Medical Center under usual traffic conditions.

You may stay in your home if your permanent address is within the SAFE ZONE. If your home is outside the SAFE ZONE, it is preferred you stay in a family or friend's home or a private rental unit with access to a sanitary bathroom and kitchen. We discourage patients from staying in a hotel or social media based rentals (such as Airbnb) because of the high costs and lack of privacy associated with these dwellings.

Please make sure you have organized a proper SAFE ZONE location before the start of your therapy. For questions or assistance with housing please call your assigned social worker.

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## Support Programs

- **Stanford Cancer Supportive Care Program**  
This comprehensive program provides numerous free classes each week to complement standard cancer treatment. Information on classes is found on the daily events calendar in the cancer center or on the website.  
<http://cancer.stanford.edu/outreach/support.html>  
or ☎650-723-4268
- **Guest Services at Stanford Health Care**  
☎650-723-6000 for more information  
Massage Therapy. Individually tailored and specific to patient’s needs. Small fee. Gift certificates available. By appointment.  
Art for Health. Art facilitator brings art materials to the bedside & works with patient to create art of your choice. No charge.  
Music Program. Bing Music Series offered twice a week, Wednesday and Friday, in the Stanford Hospital atrium. Musicians visit individual units and patient’s rooms, by request.

## Spiritual Care

Stanford Hospital and Clinics has a Chaplaincy Service that provides spiritual care 24 hours a day. Any of the CCT staff can contact the Chaplaincy Service any time you like.

Chaplains provide religious counseling, prayer, sacramental ministry and explore spiritual concerns to patients of all faiths. The Chaplaincy service is committed to providing you a resource from your own faith and traditions to help you during your Cancer Cellular Therapy and recovery.

The Chapel is located on the first floor of the hospital outside of unit D. There is also a meditation room located on the second floor of the Cancer Center.

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## Section 5—Cancer Cellular Therapy

### Informed Consent

The CCT Program is committed to improving outcomes and advancing the science of Cancer Cellular Therapy. Improvements in CCT are evaluated and developed using research studies. One potential benefit of participating in a research study is that cancer cellular therapy may work better than other therapies for your disease. Many patients also express satisfaction in contributing to the advancement of cancer treatments by participating in research studies. One risk of participation in a research study is that the cancer cellular therapy is not as effective as current therapies.

You will be given a copy of your consent form(s) to read before your scheduled appointment with a clinical research coordinator, research nurse or physician. In preparation for your consent appointment:

- Read your consent form and mark the consent with any questions you have.
- Identify someone who can come with you for your consent appointment. You will be given a lot of information and having someone else there can be very helpful.

The consent form(s) will:

- Provide a detailed description of your treatment plan
- Describe side effects of treatment
- Discuss the potential risks and benefits.
- Inform you of other studies which involve the collection of research samples and data to improve cancer cellular therapies for the future.

**Keep a copy of your signed consent form in your Guidebook**

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## Treatment Process

### Apheresis

#### Location: Infusion Treatment Area (ITA), Section F

Cancer Cellular Therapies involves manufacturing cells using your own blood. To begin you will undergo a process called apheresis, a procedure where blood is removed from you through a needle in your arm, circulated through a machine that divides whole blood into red blood cells, white blood cells, platelets and plasma (the liquid part). Then the red blood cells, platelets and plasma are returned to you. The white blood cells will then be sent to a specific laboratory where they can be genetically modified and grown.

Once your white blood cells have been genetically modified and grown, they are returned to your doctor, at which point the medical research staff will administer the cells through an intravenous infusion (IV).

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## Lymphodepleting Chemotherapy

Prior to infusing your genetically modified cells, you will receive a preparative regimen consisting of chemotherapeutic agents in order to deplete your white blood cells and create an optimal environment for cells to grow or multiply

Your consent form will state the specific chemotherapy drugs you will be receiving and provide detailed information on possible side effects. This guidebook contains information on how to manage side effects and take care of yourself after chemotherapy.

## Cancer Cellular Therapy

Shortly after completing your preparative regimen, you may be admitted into the Cancer Cellular Therapy (CCT)/ Blood and Marrow Transplant (BMT) inpatient unit, where your newly engineered cells will be administered intravenously.

All possible infusion related side effects will be discussed in your informed consent. Some side effects during and shortly after the infusion include:

- discomfort in the chest--a feeling of pressure or tightness--that will last a few minutes
- an odd taste in your mouth or an odd odor from the preservative used to protect the cells during freezing
- nausea

## After Cell Infusion

You will be closely observed for the treatment of side effects immediately after infusion of cancer cell therapy agents. You will stay inpatient until your healthcare team determines that it is safe for you to leave the hospital. After you are discharged you will be required to have a caregiver and stay within the SAFE ZONE (less than one hour by car to Stanford) for a minimum of 28 days after the cell infusion. During this time your progress will be monitored with regularly scheduled follow-up visits to either the Infusion Treatment Area (ITA) or BMT clinic at the Stanford Cancer Institute.

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## Side Effects of CCT

The objective of Cancer Cell Therapy is to enhance your body's immune system to combat aggressive forms of cancer. Like how your immune system attacks a cold or the flu, your immune system can attack cancer, however, because the immune system is greatly enhanced during your CCT regimen, the side effects can be significant. Some of the side effects that have been observed include:

- **Cytokine-release syndrome (CRS)** is a group of symptoms associated with the use of immunotherapy. CRS results from the release of substances called cytokines (proteins) into the blood circulation. These cytokines cause inflammation. CRS can affect many different parts of the body and, at minimum, resemble flu-like symptoms. Most commonly observed side effects include:
  - Fever
  - Myalgia, body aches, chills or shaking chills
  - Low blood pressure, dizziness or lightheadedness
  - Fatigue
  - Hypoxia (low levels of oxygen in your blood), difficulty breathing
- In approximately 10-25% of patients, CRS resulted in severe or life threatening symptoms requiring life support (intensive care), blood pressure medications, dialysis, or ventilators (breathing machines). Specific symptoms include:
  - General: fever (100.4F/38C or higher) and tiredness
  - Heart: rapid or irregular heart rate, decreased heart function, cardiac arrest, heart muscle injury, or very low blood pressure. These events may be life-threatening and require special medications or procedures to restore blood circulation including CPR.
  - Lungs: shortness of breath and low oxygen supply sometimes requiring additional oxygen and/or insertion of a breathing tube and placement on a ventilator to help with breathing.
  - Blood vessels: vascular leak syndrome (in which fluid in your bloodstream leaks out of circulation into other areas of your body)
  - Kidneys: low urine output and kidney failure, sometimes requiring dialysis.
  - Stomach/liver/intestines: Liver dysfunction (e.g. changes in liver enzymes), nausea, vomiting, diarrhea
- **Neurotoxicity** is a group of symptoms involving the brain and spinal cord. Most patients will have at least some of the symptoms listed below. Severe or life-

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threatening cases have occurred in approximately 10-25% of patients. Specific symptoms have included:

- Confusion, difficulty speaking or understanding speech, prolonged or pronounced sleepiness, tremors (shaky hand or other body part), facial droop, inability to control bladder or bowel, weakness in arms and/or legs, difficulty or inability to walk, anxiety and dizziness.
  - Seizures, which may be life threatening. In severe cases, they can last longer than 5 minutes and follow one after another without recovery of consciousness between them. Uncontrolled seizures may cause progressive brain damage and may result in death.
  - Neurotoxicity can lead to difficulty breathing and low oxygen levels, requiring insertion of a breathing tube and placement on a ventilator (breathing machine) and may be potentially life-threatening.
  - Leukoencephalopathy is a specific diagnosis associated with neurotoxicity in which an MRI of the brain and spinal cord show swelling within the brain and/or the spinal cord. This finding may be life threatening and accompany other symptoms of neurotoxicity above.
  - Neurotoxicity can be recurrent. Symptoms which include those found above have been observed to resolve, and later come back within a month after discharge from hospitalization. CCT patients will remain near Stanford in the safe zone for at least 28 days in case late neurotoxicity develops.
  - All patients receiving cancer cell therapy at Stanford Medical Center will receive anti-seizure medicine to prevent seizures.
- **Headache**
  - **Swelling** in arms and legs
  - **Electrolytic changes** (e.g. changes in sodium, calcium, phosphate)
  - **Infection:** Because of how cancer cell therapy works, it is expected that you will be at risk for infection. The treatment you receive may increase the risk of certain kinds of potentially life-threatening bacterial, viral and fungal infections. Some people who have received cancer cell therapy have needed to receive treatment to replace antibodies in their blood, which will help protect them from infection. Although this treatment is effective, it does not eliminate the risk of infection. In order to protect you during this high risk period, you will be asked to follow a number of guidelines designed to minimize your exposure to infectious agents.

If you are receiving YESCARTA™, please refer the Appendix A and B for the medication guide and the YESCARTA™ wallet card.

If you are receiving KYMRIA™, please refer to Appendix C and D for the medication guide and wallet card.

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## What to expect during your Cancer Cell Therapy (Inpatient)

Every morning while you are in the hospital, the CCT team will visit you and assess your status. The CCT team usually includes the attending physician, a fellow, a resident, a nurse practitioner or physician assistant, a pharmacist, physical therapist, dietician and the nurse taking care of you that day.

You need to bring a good pair of slippers or shoes with you to the hospital. The slippers or shoes should have a non-slip sole and cover your toes. Bring loose, comfortable clothing and hats or scarves. Feel free to bring items from home to decorate your room, such as photos or a favorite blanket. You can also bring a laptop computer, radio, music and DVDs.

You will not have a private room during your entire hospital stay. Private rooms are assigned based on medical judgment and considering the needs of all patients. We recognize not having a private room and room changes are stressful and apologize for any inconvenience. We appreciate your cooperation and assistance when room changes are required.

## What to expect during post-treatment follow-ups (Outpatient)

After you are discharged, you will be asked to return to the Stanford Cancer Institute for regular follow-ups through day 28 after cell infusion. These scheduled visits will occur either in the ITA or the BMT clinic. The time you spend here varies from a few hours to all day, depending on your needs and scheduling. We are committed to keeping wait times as short as possible. We suggest that you and your caregiver bring fluids, snacks and something to read to your follow-up appointments.

Upon arrival, we will:

- Record your vital signs
- Measure your weight
- Assess your symptoms and symptom management
- Perform a physical exam
- Draw blood
  - We may have you come to the lab for a blood draw early and then schedule you in the clinic when the blood test results are available.
  - This may include research sample collection.
  - Administer fluids, medications and blood products as needed

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## Section 6—Infection Prevention Measures

### Infection Prevention Measures---when to start and stop

Infection Prevention Measures	Apheresis Collection of cells	Preparative Regimen Begins	Cell Infusion	White blood cell count recovers	Day + 28	Day + 60	3 months	6 Months
<b>Avoid ill people</b>	Begin							End
<b>Frequent Hand-washing and Daily Shower</b>	Begin							End
<b>Wear HEPA Mask</b>		Begin			Stop wearing the mask <b>except</b> when you come to a hospital or clinic, crowded public spaces or near construction sites.			End
<b>Regular Diet with increase in fluids</b>		Begin			End			
<b>Do not care for Pets</b>		Begin			End			
<b>Do Not Garden</b>		Begin					End	
<b>Perform frequent mouth care</b>		Begin			End			

More detailed information about each of these infection prevention strategies can be found on the following pages.

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## Infection Prevention Strategies

### Daily Hygiene

- Proper hand washing
  - remove jewelry
  - wash the front and backs of your hands with soap and warm water— vigorously scrub for 15 seconds
  - clean under your fingernails and between your fingers
  - rinse and dry your hands with a clean towel or paper towels
  
- Wash your hands frequently
  - after using the restroom
  - before and after eating
  - after touching your hair, face, door handles, pets
  - before and after preparing food
  - after holding infants or young children
  
- Shower.
  - Apply a moisturizing lotion after you shower
  
- Clean the rectal area thoroughly after bowel movements
  - use a disposable soft washcloth (or soft toilet paper)
    - alcohol free baby wipes are also acceptable
  - barrier cream can help reduce irritation from loose bowel movements
  - notify your healthcare team for any pain, or redness
  
- Take care of your central venous catheter
  
- Perform gentle mouth care.
  - rinse with salt water 5 times a day
  - no flossing until you are 30 days post-Cancer Cellular Therapy
  - use a soft toothbrush.
  - no electric toothbrush or water pics
  
- Perform deep breathing exercises. In the hospital, we will give you a respiratory coach to help with your deep breathing exercises. While you are receiving care in the Cancer Center, walk as much as possible to exercise your lungs.

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- Protect your skin from sunlight exposure.
  - use a sunscreen of at least SPF 30
  - wear clothing to protect your skin from sunlight

## Avoid Exposure to Microorganisms

- avoid anyone who is ill with colds, flu or other infections
- follow the low microbial diet
  - *more information on the low microbial diet can be found in section seven*
- wear the HEPA filter mask
- do not clean animal cages, empty litter boxes or handle animal feces of any kind
- avoid stagnant water. Do not change the water in fish bowls or ponds.
- do not do any gardening or caring for plants in the home
- do not vacuum or dust and leave the room during vacuuming and dusting.
  - Wait 45 minutes before re-entering the room
- avoid construction sites

For the next several years there will be several major construction projects at Stanford. During construction microorganisms, such as fungus are released into the air. Wearing the HEPA filter mask and maintaining distance from active construction sites can help protect you from inhaling many of these microorganisms. Upon arrival at Stanford, BEFORE you get out of your car, remember to put on your HEPA filter mask

## Protect natural barriers to infection—your skin

- do not use rectal thermometers, rectal medications (suppositories) or enemas
- do not have **any** invasive procedures by a dentist, podiatrist surgeon or any other physician without first checking with your CCT physician

## Metric Conversions

We will record your weight in kilograms. One kilogram = 2.2 pounds.

Temperature

Centigrade	Equals	Fahrenheit		Centigrade	Equals	Fahrenheit
36.0	=	96.8		39.0	=	102.3
36.5	=	97.7		39.5	=	103.1
37.0	=	98.6		40.0	=	104
37.5	=	99.5		40.5	=	104.9
38.0	=	100.4		41	=	105.8
38.5	=	101.3				

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## What Are the Signs of Infection?

Call the CCT team **IMMEDIATELY** for any of the following:

- Fever or chills.
  - temperature > 101<sup>0</sup>F or 38.3<sup>0</sup>C or
  - a temperature of 100.4<sup>0</sup>F or 38<sup>0</sup>C sustained over one hour
  - Acetaminophen (Tylenol®) can mask a fever, so use this product only under the direction of the CCT team.
- Cold Symptoms
  - cough
  - sore throat
  - green or yellow sputum
  - runny nose
- Shortness of breath
- Any area of your skin becomes warm to touch, red, painful or swollen
- Chills after flushing the catheter
  - drainage, inflammation or tenderness around the catheter site
- Pain or burning during urination
- Any changes in your mental status, confusion, headaches, or disorientation
- Diarrhea
  - more than 4-5 loose bowel movements a day

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## When to Wear the HEPA Filter Mask?

The HEPA filter mask helps protect you from microorganisms (bacteria, viruses and fungus) that can circulate in the air (airborne). These airborne microorganisms can cause serious pneumonia if they get into the lungs.

Wear the mask

- when your white blood cell count is low
- when you leave your home or hospital room
- when you come to any hospital or clinic
- when the housekeeper is cleaning your hospital room

During what part of your Cancer Cellular Therapy do you have to wear the mask?

- from the time you start the preparative regimen until 30 days post-Cancer Cellular Therapy

## Mouth Care

After the preparative regimen, it is likely you will develop some irritation or sores in the mouth and throat. For many people, this can be the most painful part of Cancer Cellular Therapy. Your CCT team will work to relieve the pain and your job is to perform frequent mouth care to prevent infections and promote healing.

Mouth care should be done a minimum of 5 times each day

1. rinse with a bland solution (a mixture of salt and water based on your taste preference). Make the solution fresh for each use.
2. use a soft “baby” toothbrush or disposable toothbrush to gently clean
  - a. disposable toothbrushes should be discarded after one week
  - b. soft “baby” toothbrushes should be discarded after one month

## Infection Prevention While You are in the Hospital

- Visitors
  - must be healthy without colds, flu or other infections

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- will wash their hands before entering your room
- will wear a mask until your white blood cell count recovers
- we strongly discourage children under the age of 12 from visiting
  - only the children of the Cancer Cellular Therapy recipient are allowed to visit
- when you are in a semi-private room, you can only receive two visitors at a time
  - children under 12 years of age cannot visit while you are in a semi-private room
- one caregiver may spend the night when you are placed in a private room
  
- Hospital Room
  - the air is filtered to remove most microorganisms
  - no fresh flowers or plants are allowed
  - mylar balloons are allowed for 3 days, latex balloons are not allowed
  - will be cleaned on a daily basis

## Infection Prevention in Your Home

### Housecleaning

- avoid vacuuming and dusting
  - leave the room when someone else is vacuuming or dusting. Wait at least 45 minutes before returning.
- have someone change the filter on your furnace and air conditioner before you start treatment and then on a regular basis (following the manufacturers recommendations for the first year)
- bed linens should be changed once a week
- use your own towels and change them every two days

### Pets

- dogs and cats may remain in the home
  - do not clean up after or groom your pets
  - wash your hands thoroughly after contact
  - keep the pet off your bed and clothing
- birds must be relocated to another home until you are six months post-Cancer Cellular Therapy
- do not care for farm/ranch animals, small caged animals or reptiles until you are six months post-Cancer Cellular Therapy

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## Plants and Gardening

- plants may remain in the home
  - do not care for them
  - after watering, someone should wipe up any water in the rim of the pot to avoid stagnant water
- no gardening
  - no raking leaves, watering the lawn, mowing the grass, planting bulbs, digging in the soil or trimming bushes or trees

## Fans and Windows

- if you use a fan, someone else should dust the fan blades three times per week
- it is best to keep the windows closed

## Travel

- car travel
  - if the vents and windows are closed and the air is re-circulating, you do not need to wear the HEPA mask in the car
- airplane travel
  - avoid airplane travel for the first two months following Cancer Cellular Therapy

## Other Miscellaneous Activities to Be Avoided for Six Months after Cancer Cellular Therapy

- soaking in a hot tub
- swimming
- fishing
- carpentry work, woodworking
- obtaining new pets
- golfing
- having a fire in the fireplace
- having a live Christmas tree

If in doubt about the safety of an activity, ask your CCT team.

## Specific Infections of Concern

### Herpes Zoster Infection

If you had chicken pox as a child then the virus that causes chicken pox (varicella zoster virus) is still present in your body. After Cancer Cellular Therapy when the immune

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system is weak, the virus may reactivate. You will not get chicken pox again, but the virus will cause zoster or shingles.

Zoster or shingles is most likely to occur in the first year after Cancer Cellular Therapy. Zoster or shingles causes pain along a nerve path on your body and then develops into a red, itchy and blistering rash. The sooner you seek treatment, the less likely the zoster or shingles is to cause long-term pain and itching. To try and prevent zoster or shingles, you will be asked to take an antiviral medication, Acyclovir®, for the first year after Cancer Cellular Therapy.

## Respiratory Viruses

Respiratory viruses cause the flu. In people with a weak immune system, respiratory viruses can be very serious and sometimes fatal. Respiratory viruses are spread by close contact with infected individuals or contact with contaminated surfaces.

Key to prevention is:

- avoiding contact with sick individuals
- careful and thorough hand-washing as described on page 43
- vaccination of you and your family member for seasonal flu
  - You should only receive inactivated or dead viruses, no live vaccinations.

Common symptoms include:

- runny nose
- congestion
- cough
- fever
- body aches

## Pneumocystis Jiroveci Pneumonia (PJP)

Pneumocystis Jiroveci pneumonia is caused by a protozoa organism. For prevention, you may need to take a medication called Bactrim®. The Bactrim® will start after Cancer Cellular Therapy and continue until 1 year days post-Cancer Cellular Therapy. If you are allergic to Bactrim®, there are alternative medications.

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## Section 7– Diet

### The Basics

The basic principle behind the diet is the elimination of bacteria from foods by proper preparing, cooking and storing. Safe food handling techniques are essential to minimize the risk of illness from food. In brief, foods and liquids in your diet should be fully cooked, pasteurized, chlorinated, or washed thoroughly.

Cellular therapy is associated with a high metabolic demand and adequate nutrition is KEY to your recover after a cancer cellular therapy. Poor appetite is also a common symptom of cellular therapy, so it is essential to get sufficient calories, protein, fluids and nutrients to heal and avoid weight loss. Options for improving your calorie and protein intake include:

- Frequent small meals
- High calorie and high protein supplement drinks or shakes
- Feeding tubes. In some instances, placing a tube into the stomach and administering high calorie and high protein nutrition may be the best means of meeting your nutritional needs.
- Total parenteral nutrition is liquid nutrition that can be administered intravenously through your central venous catheter.

There are a number of reasons it can be difficult to eat during treatment and recovery. The following pages will provide guidance on how to optimize your oral intake while dealing with these symptoms:

- Poor appetite
- Nausea and vomiting
- Alterations in taste
- Fatigue

### What To Do When You Have Taste Changes

Taste changes are common after chemotherapy and cancer cellular therapy. Common taste alterations are foods tasting too sweet, too bitter, or a metallic taste. It takes about 3-4 months for taste buds to regenerate and food begins to taste “normal” again.

Tips for dealing with taste changes:

- Flavor foods with herbs, spices, or food seasonings
- Experiment with different food textures such as crunchy, creamy, crispy foods

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- Experiment with different foods that you don't typically eat
- Eating acidic foods such as lemon may stimulate taste buds (as long as it does not irritate your mouth)
- High protein foods and nutrition supplements are particularly important when taste changes prevent you from eating properly
- A bitter or metallic taste may be relieved with peppermints and using plastic eating utensils
- Continue to retry items that may not have worked before  
Speak with the dietitian for recommendations of specific foods you can add to your diet when you have taste alterations.

## What Foods to Avoid When You Have Diarrhea

Diarrhea is a common problem after chemotherapy and a cancer cellular therapy. It is important to avoid foods that can make diarrhea worse. In general, try to do the following:

- Eat small, frequent meals
- Eat foods that bulk stools such as applesauce, oatmeal, bananas, cooked carrots, rice, noodles, well cooked eggs, canned or cooked fruit (no skins or seeds)
- Avoid high fiber foods such as uncooked vegetables, fruit and whole grains
- Avoid foods and fluids that have lactose (milk, yogurt)
- Avoid greasy, spicy, highly seasoned and very sweet foods
- Make sure to drink plenty of fluids
- Avoid caffeinated beverages or large amounts of water.
- Instead try Gatorade®, broths, popsicles, certain nutrition supplements

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## Section 8—Taking Care of Yourself

### When Should You Call the CCT team?

- Neurological symptoms
  - Confusion
  - new tremors
  - unrelenting headaches
  - difficulty walking
- Fever or chills
  - temperature > 101<sup>0</sup>F or 38.3<sup>0</sup>C
  - or
  - two readings one hour apart of 100.4<sup>0</sup>F or 38.0<sup>0</sup>C
- Cold / Flu Symptoms
  - cough
  - sore throat
  - green or yellow sputum
  - runny nose
- Shortness of breath
- Feeling of tightness in the chest, irregular or fast heart beat
- Any area of your skin becomes warm to touch, red, painful or swollen
- Chills after flushing the catheter
  - drainage, inflammation or tenderness around the catheter site
- Pain or burning when urinating
- Unusual headaches
- Double or blurred vision
- Changes in your thinking (confusion, slowed thinking, excessive sleepiness)
- Bleeding, especially:
  - from your mouth, nose, gums, under the skin (bruising)
  - blood in your urine, stool or sputum
  - prolonged or heavy vaginal bleeding
- Difficulty emptying your bladder
- Constipation
- Any skin changes or rashes

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- Nausea or vomiting that persists and prevents you from taking in fluids or food
- Diarrhea
  - More than 4-5 loose bowel movements a day

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## Guidelines for Taking Care of Yourself

### During Apheresis

- information on apheresis can be found in your consent form
- you will need someone to drive you to and from apheresis

### During the Preparative Regimen Until Your Blood Counts Recover

1. Try to drink 3 quarts of fluid daily
2. Practice Infection Prevention Measures  
\*additional information is found in sections six and seven
  - a. avoid people who are ill
  - b. daily hygiene
  - c. wear the HEPA mask
  - d. take the prescribed antibiotics
  - e. follow the diet recommendations
  - f. do not care for pets
  - g. do not vacuum or dust
  - h. no gardening
3. Call if you get a fever or for other symptoms listed in Section 8 When you should call the CCT team
4. Do not drive or operate any heavy machinery for 8 weeks after the cellular therapy
5. Do not take medications that interfere increase the risk the bleeding by thinning the blood
  - a. this includes aspirin, Motrin®, Advil®, ibuprofen, Relieve®, Aleve®
  - b. if you have aches or pains, you can take Tylenol®
6. Get plenty of rest

If you are not in the hospital, you will need a caregiver 24 hours a day, seven days a week after discharge from the hospital

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## Precautions when you have a Low Platelet Count

*(A low platelet count puts you at risk for bleeding.)*

- Be safety conscious
  - remember some medications will make you drowsy
  - change positions slowly to decrease the risk of falling
- Avoid using a straight/safety razor. Use an electric razor. Be gentle with mouth care
  - no flossing, no toothpicks, no water pics, no electric toothbrushes
  - use a soft toothbrush
- Always wear shoes or slippers to protect your feet
- Wipe your nose gently, rather than blowing your nose
- Do not take rectal temperatures, or use rectal medications (suppositories) or receive an enema
- Avoid straining with bowel movements
  - let your CCT team know if you are constipated
- Be gentle with nail care, use nail clippers not scissors
- Use caution and care with sexual activity
  - vigorous activity may lead to bleeding
- Do not participate in contact sports
- Do not have any dental, podiatry, surgical or invasive medical procedures without checking with your CCT team
- Avoid medications that interfere with platelet function
  - this includes aspirin, Motrin®, Advil®, ibuprofen, Relieve®, Aleve®
- Do not drink alcohol until your platelet count is normal (approximately 2 months post-Cancer Cellular Therapy) as alcohol also interferes with platelet function. You should first check with your CCT physician to make sure there are not other reasons to avoid alcohol beyond two months.

If you cut yourself, put a clean cloth over the injury and apply firm pressure for 5-10 minutes. If you have a nosebleed, put pressure on the bony part of the nose for 5-10 minutes. Follow these precautions until your platelet count has returned to normal levels.

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## Section 9—Recovery

### Physical and Emotional Recovery

You and your family have been through a lot. The diagnosis and treatment of cancer is difficult emotionally, physically, spiritually and often financially. Fatigue is one of the most persistent physical symptoms following a Cancer Cellular Therapy. The best thing you can do for yourself is to start a modest program of activity and be consistent with exercising daily. The best exercise is walking. Other recommended exercises include stretching, range of motion exercises or riding a stationary bike. Avoid jogging, running or contact sports for at least six months. Slowly build back up to your usual level of activity. Listen to your body along the way so that you don't over-do it. You may want to talk with the physical therapist for ideas before you move back home. Expect the fatigue to last about six months, with full recovery of energy and stamina taking up to a full year.

Part of recovery is learning to trust your body again. It is hard to know which aches, pains and symptoms are normal and which should be reported to the CCT team. If in doubt, call the CCT team.

Following your cancer cellular therapy you may experience anxiety, frustration, depression, anger, worry and sadness. Ongoing anxiety about a relapse is a universal concern among individuals who have had cancer. The anxiety seems to be worse just before and during follow up visits. There is no magic formula for dealing with this wide range of emotions. Try to recognize these emotions and talk to your family, friends, or CCT team.

Recovery from CCT is a gradual process that takes time.

### Returning to Work

Generally, you can return to work approximately six months post-Cancer Cellular Therapy. Discuss your plans to return to work with your CCT team prior to returning to work. For some types of work such as agriculture, ranching or environments where you are exposed to chemicals, we may recommend a longer period of time before returning or we may recommend you find an alternative type of employment. Your social worker can discuss job re-training programs that may be available.

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## Taking Care of Yourself after Cancer Cellular Therapy

### Your Skin

Common skin changes after cancer cellular therapy include dryness, flaking and skin discoloration or darkening. Use a moisturizer daily to help repair the dry flaky skin. If you notice a red, blistering itchy rash, report this to your oncologist or hematologist. This rash may represent an infection called zoster or shingles.

Your skin will be more sensitive to the sun after treatment and you will more easily develop a sunburn. Avoid exposing your skin to sunlight for a year after cancer cellular therapy. When you are out in the sun wear protective clothing and always wear a sunscreen with an SPF of at least 30. Reapply the sunscreen as recommended by the manufacturer. Protecting your skin from sunlight is a good life-long habit.

### Your Mouth

Hard sour candy may relieve a dry mouth. You can also try Gatorade® gum or other sugarless chewing gums. Adding gravy or sauces to food can also help. Chemotherapy can often alter taste buds leaving food tasting bland or metallic. It can take up to 4 months for taste buds to fully regenerate. Eventually, your taste buds will recover and food will taste the way you remember it tasting.

Follow up with your dentist about six months post-Cancer Cellular Therapy or sooner if you are having problems.

### A Low Platelet Count

Until your platelet count has returned to normal levels, you should continue to avoid medications that increase the risk of bleeding by thinning the blood. These medications include aspirin, Motrin®, Advil®, ibuprofen, Relieve®, and Aleve®. Additionally, you should avoid drinking alcohol until the platelet count is normal as alcohol also thins the blood.

### Driving

You should not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get therapy because the treatment can cause sleepiness, confusion, weakness, temporary memory and coordination problems. If you are still taking medications that could cause drowsiness or impair your judgment such as narcotics for pain, medications for nausea, or anti-seizure medicine, then you should not drive until you stop these medications.

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## Who Takes Care of You After Cancer Cellular Therapy?

Generally, you will leave the Stanford area and return to your home about 28 days after your Cancer Cellular Therapy.

About 30 days post-Cancer Cellular Therapy, your primary oncologist or hematologist (the doctor who referred you to Stanford for a Cancer Cellular Therapy) will provide your cancer related care. Call and schedule an appointment with your oncologist or hematologist once you get home. The CCT team will send your oncologist or hematologist a letter describing your Cancer Cellular Therapy course and a summary of recommended follow up. If you need copies of your medical records call ☎ (650) 498-6200.

Your local medical doctor (primary care provider) will provide all your routine medical care (not cancer related). For example, if you have diabetes, or high blood pressure or you need the flu vaccine, you should see your local medical doctor.

## Routine Health Care

- Optometrist
  - schedule an appointment 6 months post-Cancer Cellular Therapy and then yearly
- Gynecologist
  - schedule an appointment 3 months post-Cancer Cellular Therapy and then yearly
  - you should discuss the risks and benefits of hormone replacement therapy if you are under 50 years of age
- Dentist
  - schedule an appointment 6 months post-Cancer Cellular Therapy and then yearly

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We hope the information in this guidebook has been useful to you. If you have suggestions on how we can improve this guidebook, please contact

**Matthew Abramian, PhD**

Clinical Research Coordinator  
Stanford Center for Cancer Immunotherapy  
Division of Cancer Cell Therapy  
Stanford University  
300 Pasteur Drive, Room HE102, MC 5623  
Stanford, CA 94305-5623  
Office: 650-736-3351  
Email: [abramian@stanford.edu](mailto:abramian@stanford.edu)

**Juliana Craig**

Clinical Research Coordinator  
Stanford Center for Cancer Immunotherapy  
Division of Cancer Cell Therapy  
Stanford University  
300 Pasteur Drive, Room HE102, MC 5623  
Stanford, CA 94305-5623  
Office: 650-736-0912  
Email: [jkcraig@stanford.edu](mailto:jkcraig@stanford.edu)

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# Cancer Cellular Therapy (CCT) Guidebook

## Cancer Cellular Therapy Dictionary

<b>Terms</b>	<b>Definition and Function</b>
anemia	Anemia is a condition in which a person has fewer than normal red blood cells. Symptoms of anemia include feeling tired, weak and short of breath.
apheresis	The collection of stem cells from the blood using a machine that can separate the blood cells.
B lymphocyte	A cell of the immune system that helps protect you from infection.
bone marrow	A liquid, similar in appearance to blood, found in the sponge like network within the large bones, for example the hip bones.
bone marrow biopsy	A procedure used to obtain a sample of bone marrow for examination.
central venous catheter	An intravenous catheter placed in a vein under the collarbone or arm vein. The catheter is used to give fluids, medications and obtain blood samples.
consent form	A document that details your treatment plan and the risks and benefits of Cancer Cellular Therapy.
Cancer Cellular Therapy	The infusion of one's own cells after they have been modified to target cancerous cells
differential	A lab test that reveals the percentages of different types of white blood cells present in the blood.
eligibility	A series of tests to see if you are healthy enough to undergo a Cancer Cellular Therapy. These tests evaluate organ (heart, lung, kidney, and liver) function, blood counts, bone marrow and the status of your disease.
graft	A collection of cells that is infused after the preparative regimen.

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hemoglobin (Hgb)	The part of the red blood cell that contains iron. Iron binds to oxygen and carries it to tissues throughout the body. Normal range for females: 11.7-15.7 g/dL Normal range for males: 13.5-17.7 g/dL
hematocrit (HCT)	The proportion of red blood cells in the body compared to the total blood volume. Normal range for females: 35-47% Normal range for males: 40-52%
infection prevention measures	Strategies that minimize the risk of infection. Key principles of infection control measures are: 1) minimize exposure to microorganisms; examples include avoiding people who are ill, reducing bacteria on the skin with daily showers and avoiding construction areas  2) protect the body's natural defenses against microorganisms; an example is avoiding cuts and scrapes which break the integrity of the skin and allow microorganisms into the body.
immune system	A system comprised of specialized cells of the body that protect us from microorganisms in the environment that cause infections.
inpatient	A person who receives care in the hospital.
microorganisms	Small organisms that can cause infections. Microorganisms include bacteria, virus, protozoa, parasite or fungus.
neutropenia	A condition in which a person has a low number of neutrophils. Neutrophils are one type of white blood cell that are important for fighting bacterial infections. Normal range is 40-60% of the total number of white blood cells.
outpatient	Your medical care is provided while you are living at home or in local housing. You come to the Cancer Center to receive care.
platelets	A blood cell that forms a clot to prevent or stop bleeding after injury. When the platelet count is low there is a risk of bleeding.

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## Cancer Cellular Therapy (CCT) Guidebook

	Normal range: 150,000-400,000/uL.
preparative regimen (lymphodepletion)	The purpose of the preparative regimen is to suppress (or weaken) the recipient's immune system enough to allow the infused cells to grow and potentially control the malignancy.
red blood cells (RBC)	A blood cell that carries oxygen throughout the body. Normal range for females: 3.8-5.2 million/uL Normal range for males: 4.4-5.9 million/uL
thrombocytopenia	A low platelet count. A low platelet count increases the risk of bleeding.
T lymphocyte	A cell of the immune system that protects your body from infection and foreign tissue.
transfusions	The infusion of different components of the blood to treat specific problems. An infusion of red blood cells is given to minimize the effects of anemia and an infusion of platelets is given to decrease the risk of bleeding.
white blood cells (WBC)	White blood cells protect the body from infection. There are many types of white blood cells including neutrophils, eosinophils, basophils, monocytes, macrophages and lymphocytes. Normal range: 4,000 –10,000/uL

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# Cancer Cellular Therapy (CCT) Guidebook

## Section 10—Appendix A: Medication Guide For YESCARTA™ Patients

<b>MEDICATION GUIDE</b>		
<b>YESCARTA (pronounced yes-kar-ta) (axicabtagene ciloleucel)</b>		
<p>Read this Medication Guide before you start your YESCARTA treatment. The more you know about your treatment, the more active you can be in your care. Talk with your healthcare provider if you have questions about your health condition or treatment. Reading this Medication Guide does not take the place of talking with your healthcare provider about your treatment.</p>		
<p><b>What is the most important information I should know about YESCARTA?</b></p> <p>YESCARTA may cause side effects that are life-threatening and can lead to death. Call or see your healthcare provider or get emergency help right away if you get any of the following:</p> <ul style="list-style-type: none"> <li>• Fever (100.4°F/38°C or higher)</li> <li>• Difficulty breathing</li> <li>• Chills or shaking chills</li> <li>• Confusion</li> <li>• Dizziness or lightheadedness</li> <li>• Severe nausea, vomiting, or diarrhea</li> <li>• Fast or irregular heartbeat</li> <li>• Severe fatigue or weakness</li> </ul> <p>It is important to tell your healthcare provider that you received YESCARTA and to show them your YESCARTA Patient Wallet Card. Your healthcare provider may give you other medicines to treat your side effects.</p>		
<p><b>What is YESCARTA?</b></p> <p>YESCARTA is a treatment for your non-Hodgkin lymphoma. It is used when you have failed at least two other kinds of treatment. YESCARTA is different than other cancer medicines because it is made from your own white blood cells, which have been modified to recognize and attack your lymphoma cells.</p>		
<p><b>Before getting YESCARTA, tell your healthcare provider about all your medical problems, including if you have or have had:</b></p> <ul style="list-style-type: none"> <li>• Neurologic problems (such as seizures, stroke, or memory loss)</li> <li>• Lung or breathing problems</li> <li>• Heart problems</li> <li>• Liver problems</li> <li>• Kidney problems</li> <li>• A recent or active infection</li> </ul> <p>Tell your healthcare provider about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.</p>		
<p><b>How will I receive YESCARTA?</b></p> <ul style="list-style-type: none"> <li>• Since YESCARTA is made from your own white blood cells, your blood will be collected by a process called “leukapheresis” (loo-kah-fur-ee-sis), which will concentrate your white blood cells.</li> <li>• Your blood cells will be sent to a manufacturing center to make your YESCARTA.</li> <li>• Before you get YESCARTA, you will get 3 days of chemotherapy to prepare your body.</li> <li>• When your YESCARTA is ready, your healthcare provider will give it to you through a catheter placed into your vein (intravenous infusion). The infusion usually takes less than 30 minutes.</li> </ul>		

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# Cancer Cellular Therapy (CCT) Guidebook

<ul style="list-style-type: none"> <li>You will be monitored where you received your treatment daily for at least 7 days after the infusion.</li> <li>You should plan to stay close to the location where you received your treatment for at least 4 weeks after getting YESCARTA. Your healthcare provider will help you with any side effects that may occur.</li> <li>You may be hospitalized for side effects and your healthcare provider will discharge you if your side effects are under control, and it is safe for you to leave the hospital.</li> <li>Your healthcare provider will want to do blood tests to follow your progress. It is important that you do have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.</li> </ul> <p><b>What should I avoid after receiving YESCARTA?</b></p> <ul style="list-style-type: none"> <li>Do not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get YESCARTA because the treatment can cause sleepiness, confusion, weakness, temporary memory and coordination problems.</li> <li>Do not donate blood, organs, tissues, and cells for transplantation.</li> </ul>
<p><b>What are the possible or reasonably likely side effects of YESCARTA?</b></p> <p>The most common side effects of YESCARTA include:</p> <ul style="list-style-type: none"> <li>Fever (100.4°F/38°C or higher)</li> <li>Low white blood cells (can occur with a fever)</li> <li>Low red blood cells</li> <li>Low blood pressure (dizziness or lightheadedness, headache, feeling tired, short of breath)</li> <li>Fast heartbeat</li> <li>Confusion</li> <li>Difficulty speaking or slurred speech</li> <li>Nausea</li> <li>Diarrhea</li> </ul> <p>These are not all the possible side effects of YESCARTA. Call your healthcare provider about any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.</p>
<p><b>General information about the safe and effective use of YESCARTA</b></p> <p>Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about YESCARTA, talk with your healthcare provider. You can ask your healthcare provider for information about YESCARTA that is written for health professionals. You can get additional information by contacting Kite at 1-844-454-KITE (5483) or at <a href="http://www.Yescarta.com">www.Yescarta.com</a>.</p>
<p><b>What are the ingredients in YESCARTA?</b></p> <p><b>Active ingredients:</b> axicabtagene ciloleucel.</p> <p><b>Inactive ingredients:</b> albumin (human); DMSO.</p>

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# Cancer Cellular Therapy (CCT) Guidebook

## Appendix B YESCARTA™ Wallet Card



### Patient Wallet Card

**Carry this card with you at all times. SHOW THIS CARD if you go to the emergency room or see any physician.**

Tell any healthcare provider that sees you that you are being treated with YESCARTA™.

Stay within close proximity (within 2 hours) of the location where you received your treatment for at least 4 weeks after getting YESCARTA™.

#### Important Information for Healthcare Providers

Name of treating oncologist:

\_\_\_\_\_

Office phone:

\_\_\_\_\_

After-hours phone:

\_\_\_\_\_

Date of YESCARTA™ (axicabtagene ciloleucel) infusion:

\_\_\_\_\_

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# Cancer Cellular Therapy (CCT) Guidebook

• This patient has received YESCARTA™, which is a CD19-directed genetically modified autologous T-cell immunotherapy

• YESCARTA™ can cause cytokine release syndrome (CRS) and neurologic toxicities, which may be fatal or life threatening. CRS may involve any organ system



• Contact the patient's oncologist immediately for further information

## Patient Information

YESCARTA™ can cause side effects that can lead to death.

**Call or see your oncologist or get emergency help RIGHT AWAY if you have any of these symptoms:**

- Fever (100.4°F/38°C or higher)
- Difficulty breathing
- Chills or shaking chills
- Confusion
- Dizziness or lightheadedness
- Severe nausea, vomiting, or diarrhea
- Fast or irregular heartbeat
- Severe fatigue or weakness

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# Cancer Cellular Therapy (CCT) Guidebook

## Appendix C Medication Guide for Kymriah™ Patients

<p><b>MEDICATION GUIDE</b>  <b>KYMRIAH™ (pronounced <i>KIM-RYE-AH</i>)</b>  <b>(tisagenlecleucel)</b></p>		
<p>Read this Medication Guide before you start your KYMRIAH treatment. The more you know about your treatment, the more active you can be in your care. Talk with your healthcare provider if you have questions about your health condition or treatment. Reading this Medication Guide does not take the place of talking with your healthcare provider about your treatment.</p>		
<p><b><u>What is the most important information I should know about KYMRIAH?</u></b></p> <p>KYMRIAH may cause side effects that are severe or life-threatening. Call your healthcare provider or get emergency help right away if you get any of the following:</p> <ul style="list-style-type: none"> <li>• difficulty breathing</li> <li>• fever (100.4°F/38°C or higher)</li> <li>• chills/shaking chills</li> <li>• confusion</li> <li>• severe nausea, vomiting, diarrhea</li> <li>• severe muscle or joint pain</li> <li>• very low blood pressure</li> <li>• dizziness/lightheadedness</li> </ul> <p>It is important that you tell your health care providers that you have received KYMRIAH. Your healthcare providers may give you other medicines to treat your side effects.</p>		
<p><b><u>What is KYMRIAH?</u></b></p> <p>KYMRIAH is made from your own white blood cells and is a prescription cancer treatment used in patients up to 25 years old who have acute lymphoblastic leukemia (ALL) that is either relapsing (went into remission, then came back) or refractory (did not go into remission after receiving other leukemia treatments). It is also used in patients with non-Hodgkin lymphoma that has relapsed or is refractory after having at least two other kinds of treatment.</p>		
<p><b><u>How will I get KYMRIAH?</u></b></p> <p>Since KYMRIAH is made from your own white blood cells, your healthcare provider has to take some of your blood. This is called "leukapheresis." It takes 3 to 6 hours and may need to be repeated. A tube (intravenous catheter) will be placed in your vein to collect your blood.</p> <p>Your blood cells are frozen and sent to the manufacturing site to make KYMRIAH. It takes about 3-4 weeks from the time your cells are received at the manufacturing site and shipped back to your health care provider, but the time may vary.</p> <p>Before you get KYMRIAH, your healthcare provider may give you chemotherapy for a few days to prepare your body.</p> <p>When your body is ready, your healthcare provider will give you KYMRIAH through a tube (intravenous catheter) in your vein. This usually takes less than one hour.</p> <p>You should plan to stay within 2 hours of the location where you received your treatment for at least 4 weeks after getting KYMRIAH. Your healthcare provider will check to see if your treatment is working and help you with any side effects that occur.</p>		

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# Cancer Cellular Therapy (CCT) Guidebook

## **What should I avoid after receiving KYMRIA?**

- Do not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get KYMRIA because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures.
- Do not donate blood, organs, tissues and cells for transplantation.

## **What are the possible or reasonably likely side effects of KYMRIA?**

The most common side effects of KYMRIA are:

- difficulty breathing
- fever (100.4°F/38°C or higher)
- chills/shaking chills
- confusion
- severe nausea, vomiting, diarrhea
- severe muscle or joint pain
- very low blood pressure
- dizziness/lightheadedness
- headache

KYMRIA can increase the risk of life-threatening infections that may lead to death. Tell your healthcare provider right away if you develop fever, chills, or any signs or symptoms of an infection.

KYMRIA can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets). After treatment, your healthcare provider will test your blood to check for this. Tell your healthcare provider right away if you get a fever, are feeling tired, or have bruising or bleeding.

Having KYMRIA in your blood may cause a false-positive HIV test result by some commercial tests.

These are not all the possible side effects of KYMRIA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## **General information about the safe and effective use of KYMRIA.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

Do not use KYMRIA for a condition for which it was not prescribed.

Talk to your healthcare provider about any concerns. You can ask your healthcare provider for information about KYMRIA that is written for healthcare professionals.

For more information, go to [KYMRIA.com](http://KYMRIA.com) or call 1-844-NVS-CART (1-844-687-2278).

Manufactured and Distributed by: **Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936.**

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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# Cancer Cellular Therapy (CCT) Guidebook

## Appendix D Wallet Card for Kymriah™ Patients

NOVARTIS  
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- Confusion  
- Chills/shaking chills  
- High fever  
- Fever (100.4°F/38°C or higher)  
- Difficulty breathing  
- Severe nausea, vomiting, diarrhea  
- Severe muscle or joint pain  
- Very low blood pressure  
- Dizziness/light-headedness  
- Headache

**SIGNS AND SYMPTOMS MAY INCLUDE:**

**Call your oncologist or go to the emergency room if these signs appear.**

**Patient Information**  
Kymriah may cause side effects that are severe or life-threatening.

### PATIENT WALLET CARD

**Have This Card With You At All Times  
Show It To Any Doctor That Sees You And When  
You Go To The Hospital**

You should plan to stay within 2 hours of the location where you received your treatment for at least 4 weeks after getting Kymriah. Your healthcare provider will check to see if your treatment is working and help you with any side effects that occur.

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#### INFORMATION FOR THE HEALTHCARE PROVIDER

This patient has received Kymriah (CAR-T cell) therapy

**Following Kymriah treatment, Cytokine Release Syndrome (CRS) can happen. It may include neurological toxicities.**

**Please contact his/her treating oncologist in the following situations:**

- before giving steroids or cytotoxic medications
- if the patient has a serious infection
- before the patient undergoes an invasive procedure

fold

Date received Kymriah: \_\_\_\_\_

Oncologist Name (for Kymriah therapy): \_\_\_\_\_

Phone Number: \_\_\_\_\_

Kymriah is a CD19-directed genetically modified autologous T Cell immunotherapy indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse and adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Limitation of Use: KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma

**KYMRIAH**  
(tisagenlecleucel) CAR-T cell

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