

Cellular Immunotherapy Overview

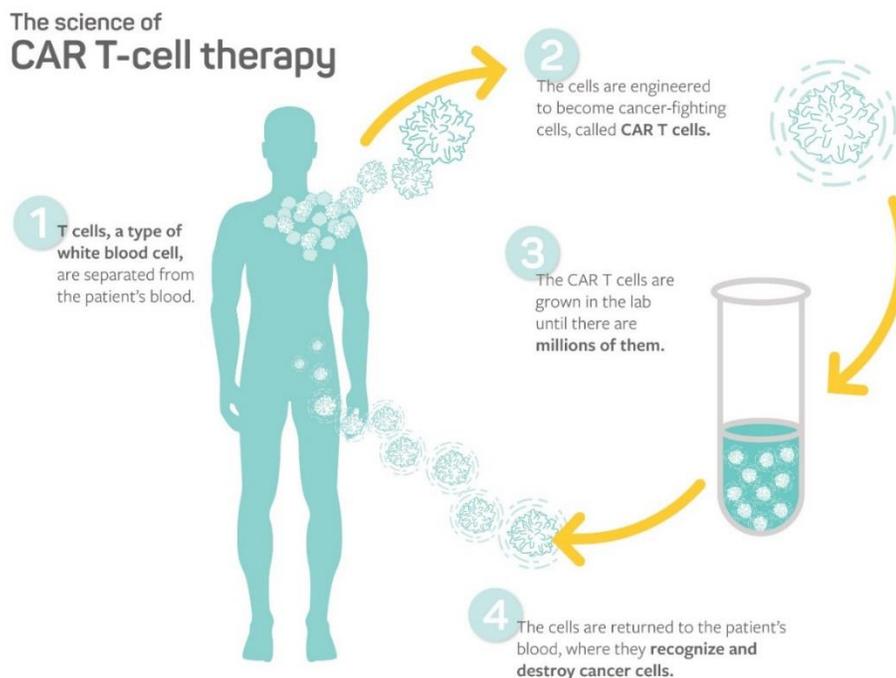
Bezos Family Immunotherapy Clinic

Introduction

Your immune system protects your body against infection and abnormal cellular changes, such as cancer. Cancer cells can hide from the immune system and even trick it into helping—rather than harming—these cells. Immunotherapy helps your immune system work harder and smarter to attack cancer. We offer 3 types of cellular immunotherapies; some of them are approved by the US Food and Drug Administration (FDA) and others are in clinical trials:

- Chimeric antigen receptor (CAR) T-cell
- Tumor Infiltrating Lymphocytes (TIL)
- T-cell receptor (TCR)

Each of these therapies changes the T cells in your immune system to become disease-fighting cells.



The image above describes how CAR T-cell therapy works.

What you can expect

Your experience is unique

The information below is meant to give you a general idea of the cellular immunotherapy experience at SCCA. Keep in mind that your experience is unique. It will differ from others based on your disease, treatment plan, and response to treatment.

Visit scca.io/imtxvideo to watch a video about the cellular immunotherapy experience at SCCA.

Phases of immunotherapy

Cellular immunotherapy is made up of several phases:

- Evaluation
- Cell collection or cell harvesting
- Cell engineering
- Chemotherapy
- Cell infusion
- Monitoring for side effects
- Follow-up
- Long term follow-up

Your appointments

During each of the phases noted above, you may have one or more appointments. It is important that all appointments are kept as scheduled. We suggest bringing someone with you to help listen and take notes. Most appointments will take place at SCCA. Some of your outpatient care may be provided at the University of Washington Medical Center (UWMC). Your care team will talk to you about your specific treatment plan and appointment locations. If needed, your inpatient care will be provided at SCCA Hospital or UWMC, which has a team of cellular immunotherapy nurses and physicians, just like our outpatient clinic.

Your location during treatment

For your safety, from the time you start chemotherapy, until the time you are discharged from day-to-day care, you are expected to live within a 30-minute drive to SCCA. If you are coming to Seattle from out of town, we recommend arranging temporary housing as soon as you know your arrival date. You may not be allowed to drive for 4 to 8 weeks following your cell infusion, depending on your treatment plan and condition. Your care team will discuss this with you in more detail.

We encourage you to visit our website, seattlecca.org/housing-information, to learn about SCCA's housing options and to view our housing guide. If you choose a different accommodation, there are a variety of hotels and extended-stay options within a 30-minute drive to our clinic.

Your caregiver

Due to the intensity of the treatment, you will need to have a caregiver with you 24 hours a day during chemotherapy, cell infusion, and for several weeks after your cell infusion. Your care team will determine how long you will need a caregiver following cell infusion (generally, based on our experience with other cellular immunotherapy patients, it's about 4 weeks). This is the same time that you are also expected to live within a 30-minute drive to SCCA.

A caregiver provides around-the-clock monitoring, emotional support, and physical care, if needed. You may find it helpful to have one main caregiver, with assistance from other family members, friends, or hired caregivers. Before treatment starts, your team will teach you and your caregiver the symptoms to look for as you undergo treatment.

We recommend bringing your caregiver to appointments even before you start chemotherapy to meet your care team and learn about your treatment plan. See *Caring for a Person Receiving Cellular Immunotherapy* for more information about the role of a caregiver during treatment.

Evaluation

As a first step, you will meet with your care team to discuss your medical history, current disease status, and undergo a series of tests to evaluate your health and eligibility to receive cellular immunotherapy. Examples of the types of tests or procedures you might have include:

- Bone marrow biopsy
- Blood draws
- Chest X-ray
- DEXA bone scans
- EKG (electrocardiogram)
- Lumbar puncture
- MUGA scan or echocardiogram
- PET/CT scan
- Pulmonary function tests

After this is complete, you will have a conference with your care team to discuss whether cellular therapy is a good treatment option for you. We recommend bringing your caregiver with you to this meeting. Your physician will review information about treatment and side effects. You will be asked to sign consent forms before beginning therapy. The conference is a time for you to ask questions about the forms you are signing and about your treatment. Please read the forms carefully, but do not write on or sign them before your meeting.

Cell collection

T cells are collected from you through either apheresis (ay-fer-ee-sis) or a surgical procedure. Your cells will be collected through apheresis if you are getting CAR T-cell or TCR therapy. Your cells will be collected (also called “harvested”) through a surgical procedure if you are getting TIL therapy.

During apheresis, blood is taken from your body, sent through the apheresis machine that separates and collects your T cells, and the rest of the cells are returned to your bloodstream. Apheresis generally takes 3 to 6 hours. Your apheresis nurse will have a better idea of how long your cell collection will take once you have started the process. Apheresis will take place on the 5th floor of the SCCA clinic.

After your cells are collected or harvested, they are sent to a lab where scientists work to turn them into cancer-fighting cells.

Cell engineering

It generally takes 2 to 4 weeks for scientists/manufacturers to grow your new cells in the lab. Your care team will let you know how long you can expect to wait to receive your cells. During this phase, you will be seen in our clinic to make sure your body is ready for your treatment. If your care team approves and you live out of town, you may be able to go home until your cells are ready.

Chemotherapy

Before receiving your new T cells, you may get lymphodepleting chemotherapy. The purpose of this is to decrease the number of immune system cells in your body to create space for your new cells. You will meet with a nurse before chemotherapy to talk about potential side effects and how to manage them.

You will receive your chemotherapy through a central line. A central line allows you to have long-term intravenous (IV) access for the chemotherapy, cell infusion, and administration of medications that might be needed after cell therapy. If you do not have a central line, you will have one placed (see *Central Line Care* for more information).

Cell infusion

A few days after chemotherapy, your cells are infused. Depending on your treatment plan, your infusion may take place at the Immunotherapy Clinic at SCCA, or at the UWMC or SCCA Hospital. Once your cells are infused, you will need to be monitored for side effects.

Monitoring for side effects

Cellular immunotherapy can have serious side effects such as high fevers, unstable blood pressure, and changes in speech, behavior, and memory. Based on our experience, these side effects typically occur within the first 2 weeks after your infusion. We will give you contact information for who to call, day or night, if you experience urgent side effects.

You and your caregiver will be taught how to monitor for fever and what to do if you get one. If you experience a fever after receiving your T cells, you will be admitted to SCCA Hospital or UWMC. Your caregiver is not required to be with you if you are admitted, but you may find it comforting to have your caregiver with you in the hospital. UWMC and SCCA Hospital are designed for them to stay overnight.

The two main side effects that you will be monitored for are **cytokine release syndrome (CRS)** and **neurotoxicity**.

CRS is a severe inflammatory response that can lead to dangerously high fevers and extremely low blood pressure. Sometimes it goes away on its own with medical intervention and monitoring. But in rare cases, it can be severe and fatal. The most common first symptom of CRS is a fever. If you get a fever, you will be admitted to the hospital for monitoring. Severe symptoms may require intensive care unit (ICU) level care.

Another potential side effect is **neurotoxicity**. If this occurs, you will be admitted to the hospital. The cause of neurotoxicity is unknown, but it typically develops after CRS. When you have neurotoxicity, you can experience symptoms such as confusion, difficulty speaking, memory loss, unsteadiness, or seizures. Often, these symptoms may last less than a few days, are mild, and only need close monitoring. Sometimes, the symptoms may be more severe and last more than a few days. For example, you may not remember where you are, not recognize the people around you, or have difficulty getting to the bathroom on your own.

For symptoms of both CRS and neurotoxicity, you may be treated with steroids which can help slow down the growth of T cells. You may also receive medications to help reduce the risk of seizures during treatment.

You may feel weak and fatigued, which can impact your ability to perform your routine, daily activities. Based on the type and severity of side effects you experience, you may need to have special equipment at home (such as a walker, shower chair, or raised toilet seat) and you may require additional help, home care, and/or a physical therapist. Your care team can help you access these resources.

Follow-up

We are committed to providing you the best possible treatment and follow-up care. Following your infusion of T cells, your care team will monitor you closely. Most patients visit the clinic daily. If you are in the hospital, a Transition nurse will coordinate follow-up appointments with your care team from the immunotherapy clinic.

Based on your progress and treatment plan, we will determine your recommended follow-up plan after you leave SCCA. We will provide your referring physician a discharge summary. You will receive a packet with your medication list and most recent lab values, other medical records, and a disk with your radiology images.

Long term follow-up

After you are discharged from the clinic, the Immunotherapy Long Term Follow-up (LTFU) staff will be a resource for you and your local provider. They are available during business hours to answer your questions and concerns related to cellular immunotherapy. You can reach LTFU staff by email at imtxlftu@fredhutch.org or by phone at (206) 667-5811.

You may be asked to participate in one or more long-term follow up studies. These types of studies help us learn about the long-term effects of cellular immunotherapy. The follow-up may be done through e-mail, regular mail, and/or appointments with your primary care physician, oncologist, or SCCA care team.

Frequently asked questions

What is a T cell?

A T cell is a type of white blood cell in the immune system that destroys viruses, bacteria, and cancer. Sometimes, T cells don't do their job, and viruses, bacteria, and cancer can take over. Using cellular immunotherapy, scientists alter T cells to become cancer fighters¹.

What is tumor infiltrating lymphocyte (TIL) therapy?

Tumor Infiltrating Lymphocytes (TIL) are T cells that can be found in your tumor. During TIL therapy, TILs are collected or "harvested" from your tumor and treated with substances that make them grow to large numbers quickly. The cells are given to you and used to target and kill cancer cells².

What is CAR T cell therapy?

CAR T-cell therapy is similar to TIL therapy, but your T cells are changed in the lab so that they make a type of protein known as CAR before they are grown and given back to you. CAR stands for chimeric antigen receptor. CARs are designed to allow the T cells to attach to specific proteins on the surface of the cancer cells, improving their ability to attack the cancer cells².

What is T cell receptor (TCR) therapy?

TCR is similar to CAR T-cell therapy, but instead of attaching to specific proteins on the surface of the cancer cells, TCRs can recognize tumor specific proteins on the inside of the cells.

How effective is cellular immunotherapy for cancer patients?

When you meet with our team, we will go over the potential benefits and risks of cell therapies and discuss if they are the right treatment for you.

¹<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/t-cell>

² <https://www.cancer.gov/about-cancer/treatment/types/immunotherapy/t-cell-transfer-therapy>

How much do cellular therapies cost?

The cost varies based on the intensity of your treatment and insurance coverage. Our Intake team will discuss insurance and other financial considerations with you before your first appointment. You can also contact SCCA's Patient Financial Services team directly to help you understand what treatments might cost you.

What is the FDA?

The FDA is the US Food and Drug Administration. The FDA makes sure that safe and effective drugs are available to improve the health of people in the United States³.

What is a clinical trial?

A clinical trial is a type of research study that tests how well new medical approaches work in people⁴. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Clinical trials for drugs and medical devices often occur in 4 phases, and each phase has specific research goals. The goals of each phase are to evaluate:

Phase I: Safety, dosage, and side effects

Phase II: Side effects and effectiveness

Phase III: Effectiveness compared to standard treatment

Phase IV: Long term effects

If you are not a Bezos Family Immunotherapy Clinic patient, please contact our Intake team with questions at 1 (800) 804-8824. If you are a patient at our clinic, please contact your care team with any questions about your immunotherapy experience at SCCA.

³ <https://www.fda.gov/drugs>

⁴ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/clinical-trial>