

Understanding the CAR T Cell Therapy Treatment Experience

The safety and efficacy of agents and/or uses under investigation have not been established. There is no guarantee that the agents will receive health authority approval or become commercially available in any country for the uses being investigated.

Chimeric antigen receptor (CAR) T cell therapy is a personalized approach to treating certain blood cancers. Unlike traditional cancer therapies, CAR T cell therapies are often administered as a one-time treatment made from a patient's own T cells, which are "reprogrammed" during a sophisticated manufacturing process to help the T cells recognize and fight cancer cells.



Patients and caregivers are provided education and support by their care team to prepare for treatment and potential side effects

When a patient with a certain type of blood cancer has experienced disease relapse, meaning their cancer has progressed or is no longer responding to previous therapies (refractory), their doctor may recommend the use of CAR T cell therapy. With a one-time treatment, this type of therapy can help a patient achieve a positive response. Once a patient's eligibility is confirmed and the patient and doctor decide to move forward with a CAR T cell therapy, the process of creating the therapy from the patient's T cells begins.



Step 1: T Cell Collection

T cells, which are a type of white blood cell that function as key fighters in the immune system, are removed through a process called apheresis or leukapheresis, which takes several hours. During the T cell collection, blood is withdrawn and T cells are separated from other blood components. The remaining blood is then infused back into the patient.



Step 2: T Cell Activation During Manufacturing

The collected T cells are shipped to a specialized cell therapy manufacturing facility where they undergo genetic "reprogramming" to become CAR T cells that have receptors (or hooks) added to the T cells to help recognize and fight cells containing a specific antigen on the surface of the target cell, including normal and cancer cells. The CAR T cells are then multiplied to create the appropriate dose consisting of millions of CAR T cells, which then undergo rigorous testing and quality control before being shipped back to the patient at a CAR T treatment center. The manufacturing process can take several weeks to complete.



Step 3: Preparing for Treatment

A few days before receiving their CAR T cell therapy, patients receive low-dose chemotherapy, known as lympho-depleting chemotherapy, to help prepare the body to receive the reprogrammed CAR T cells. This helps to create space in the patient's immune system to accept the CAR T cells and target the cancer cells.



Step 4: CAR T Cell Therapy Infusion

At the treatment center, patients receive their personalized CAR T cells with one dose. The process usually takes about an hour or less. From there, the CAR T cells may expand and travel throughout the body to attack the target cells.



Step 5: Monitoring

All patients who receive a CAR T cell therapy are monitored closely by their care team for possible side effects, which may be severe, life-threatening or fatal. Time at the hospital will vary based on the individual patient. Patients need to stay in proximity to the treatment center for at least four weeks, and may return home when their doctor says that it is safe to do so. However, they may need to stay nearby or return to the hospital if side effects develop after returning home.



Step 6: Continued Follow Up

The patient's care team will continue to follow up with a patient via phone calls and in-person appointments to assess whether the CAR T cell therapy is working and to watch for side effects. Patients will see their doctor for ongoing follow-up after treatment, though the frequency of follow-ups may vary and are determined by the doctor. A patient's caregiver will also play a critical role in helping monitor the patient for potential side effects.

Select Side Effects of CAR T Cell Therapy

CAR T cell therapies are still being studied in clinical trials. Safety information for these therapies is still evolving.

The side effects of CAR T cell therapy will vary from person to person, and can be mild, moderate, severe, or may even cause death. Patients should always speak to their doctor about any side effects they may experience.

There are many side effects associated with CAR T cell therapy. Two of the potential serious side effects patients need to be aware of include:

Cytokine Release Syndrome (CRS)

CRS is a systemic inflammatory response that can happen in the first few days to several weeks after a patient's CAR T cells are put back into their body. **Symptoms may include, but are not limited to:**

- Fever (pyrexia)
- Fatigue
- Nausea
- Chills
- Low blood pressure (hypotension)
- Headache
- Swelling
- Rapid heartbeat (tachycardia)
- Muscle/joint pain (myalgia/arthralgia)
- Weakness (asthenia)
- Low oxygen level (hypoxia)
- Breathing difficulty (dyspnea)
- Stomach pain
- Confusion

Neurotoxicity

Neurotoxicity can cause adverse functional or structural change in the nervous system. It can happen in the first few days to several weeks after a patient's CAR T cells are put back into their body. **Symptoms may include, but are not limited to:**

- Confusion
- Difficulty or inability to speak
- Difficulty staying awake
- Loss of coordination
- Agitation
- Difficulty walking
- Shaking
- Seizures
- Headache
- Memory loss

These are not all of the side effects associated with CAR T therapies, and the side effects are different from product to product. Patients should talk to their doctor to understand the side effects for specific CAR T cell therapies.

Deaths have been reported in clinical trials of CAR T cell therapies.

Some CAR T cell therapies are FDA approved, but many are still being studied in clinical trials.

Learn more [here](#) about how CAR T cell therapy works and consult with a physician