# CAR T-Cell Therapy

## Idecabtagene vicleucel (Abemca®)

**Chimeric antigen receptor** (CAR) T-cell therapy is a type of immunotherapy that uses a patient's own T cells to recognize and kill cancer cells. The immune system is made up of 3 sub-types of white blood cells (lymphocytes): B lymphocytes to fight infection, T lymphocytes and natural killer (NK) cells to kill infected or cancerous cells.

## About Abecma®

Abecma® is a prescription medication that is approved by the Food and Drug Administration (FDA) to treat adult patients with relapsed or refractory multiple myeloma, when:

- You have tried two or more kinds of treatments that have not worked or have stopped working **AND**
- You have received at least one therapy from each of these drug classes:
    - An immunomodulatory agent
    - A proteasome inhibitor
    - An anti-CD38 antibody

With this therapy, white blood cells (T cells) are removed from your blood and altered in a lab to have specific receptors called CARs made on the surface of the T cells. The T cells are changed to turn against your tumor cells, multiplied and then frozen. This change:

- Tells your T cells to go to the tumor cells, "turn on" and possibly attack them.
- Results in a genetic change to your T cells. This process is called a gene transfer.
- Allows the T cells to know which cells are tumor cells and which cells are your normal antibody-producing cells, called B cells.

Chemotherapy is given first to prepare you for the CAR T-cell infusion. The changed T cells, are then given back to you through an IV infusion. You will get one dose of these T cells.

Below is a common treatment plan for CAR T-cell therapy. Talk to your physician, nurse or a cell therapy coordinator if you have any questions or concerns.

# Patient Education

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The days before the CAR T-cell infusion are counted down. For example: -5,-4, -3, -2, and -1. The day of the infusion is **Day 0**. The days after the infusion are counted up as +1, +2, +3 and so on.

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| **2 to 6 Weeks Before CAR T-Cell Infusion (Day 0)** | • Patient referral/recommended for therapy<br>• Patient financially cleared<br>• Informed consent completed<br>• Patient scheduled for apheresis T-cell collection<br>• Harvested T cells sent to lab<br>• No steroids at least 1 week before cell infusion |
| **Conditioning Chemotherapy (Days -6 or -5)** | • Chemotherapy can be given as an inpatient or outpatient. Your doctor will decide if your therapy will be inpatient or outpatient based on your condition.<br>• Chemo can start on day -6 or day -5 and you can get 3 to 4 days of chemo followed by 2 days of rest. |
| **CAR T-Cell Infusion (Day 0)** | You will receive your infusion. |
| **After Infusion (Day 0 to Day +14)** | What to expect after your infusion:<br><br>• During your hospital stay, we will check your vital signs every 4 hours (or more frequently, dependent on patient clinical presentation).<br>• You will perform daily hygiene (shower, mouth care, wash hands and foot care).<br>• You will sit up in chair and walk at least 3 times a day<br>• You will use the incentive spirometer every hour at least 10 times while you are awake.<br>• Your medical team may ask you to write a sentence every day as part of your neuro assessment.<br>• You will increase your fluids by drinking at least 6 to 8 glasses a day unless you are on fluid restrictions.<br><br>Watch for possible side effects.<br><br>• **Cytokine Release Syndrome (CRS)** – a serious condition related with CAR T-cell therapy. Cytokines are proteins that are released by the T cells. They communicate with other special immune system cells to kill cancer cells. Cytokines can cause inflammation, similar to a severe infection. Possible signs and symptoms of CRS include:<br>– Fever of 100.4°F (38.0°C) or higher, increased fatigue, not feeling well and chills |

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| | – Shortness of breath, rapid breathing and fast heart rate related to low oxygen supply in the blood<br>– Abnormal heart rate or rhythm, low blood pressure, congestive heart failure and heart failure related to low or high ejection fraction (measurement of the amount of blood pumped in and out of the heart)<br>– Nausea, vomiting and diarrhea<br>– Liver damage, injury, inflammation and elevated liver enzymes<br>– Kidney damage, injury, decreased urine output<br>– Skin rash<br>– Bleeding disorder in which the body is unable to form blood clots and can lead to excessive or prolonged bleeding.<br><br>Treatment of CRS symptoms is based on a grading scale. Grade 2 or more is treated with the following medicines:<br>• Tocilizumab (Actemra®)<br>• Corticosteroids<br><br>Also, some medicines may require you to sign a consent form.<br><br>• **Neurologic Toxicity** – a serious side effect that affects the nervous system and can change how the brain works or its structure, making it hard to think clearly. It can be serious and life threatening. Symptoms include confusion, seizures, shaking or twitching, difficulty speaking or slurred speech, disorientation and severe sleepiness. |
| **After infusion (Day +15 to Day +25)** | **Possible Discharge**<br>Continue to check temperature twice a day, do daily hygiene, walking, incentive spirometer and drink fluids.<br>Continue to watch for and manage possible side effects of CRS and neurologic toxicity. Your discharge may be sooner but will depend on how you are doing. |
| **Discharge (Day +30)** | Your doctor will order lab tests to assess how you are doing and discuss your long-term follow up plan. |

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## General Information

The information below explains the pre-infusion phase, the T-cell collection process, the inpatient phase and the outpatient recovery phase.

## Before the Treatment

### Pre-infusion

The pre-infusion phase involves a few needed steps before a CAR T-cell infusion can be offered. We will need to confirm financial approval and make sure the stage of disease will respond to treatment.

For some, the pre-infusion phase can be very short and for others, the process could take weeks to months. This usually depends on if there are problems or delays with financial clearance or disease control. Your cell therapy coordinator will guide you through this process.

### Collection of Therapeutic Cells by Apheresis

We will need to collect T cells from your body to make the Abecma®. A procedure called apheresis is used to collect your T cells. A separate consent is needed for the apheresis procedure.

During apheresis, one IV line moves blood out of the body and filters it through the apheresis machine. Another IV line returns the blood back into the body. The apheresis machine collects the cells by choosing cells of a certain size as they move through the machine. An apheresis procedure takes about 4-5 hours. Make sure you drink plenty of fluids so you are hydrated the day of your consult and the day of your apheresis procedure.

Apheresis begins with the insertion of a tube (intravenous catheter) in your arm. This catheter is used to transfer blood from you to a centrifuge machine that separates out the therapeutic cells. These cells are collected in a collection bag and the remaining blood components are returned to you through an IV in your other arm. In some cases, a central venous catheter may be required. If a central venous catheter is needed, you will be asked to sign a separate consent form.

While you are waiting for your cells, it may be necessary to give you more chemotherapy. This may increase the risk of adverse events during the pre-infusion period.

### Pre-admission Testing

You will need a series of tests before you are admitted for your CAR T-cell infusion. All of the tests evaluate your disease status or personal health. You may have recently had some of these tests already, however, it may be necessary to do them again. Most times, test results must be from within 30 to 45 days of your infusion. The results tell the team if you have any health conditions that may need more evaluation.

Some common tests are:

- Echocardiogram (ECHO): looks at blood flow through the heart
- Electrocardiogram (EKG): looks at electrical activity of the heart
- Pulmonary function test (PFT): checks the health and strength of the lungs
- Computerized Tomography (CT) or Positron Emission Tomography (PET) scan: checks location and activity of some diseases
- Blood and urine tests: check blood counts, including a pregnancy test for women of childbearing age and who are not in complete menopause

Your cell therapy coordinator and treatment team will tell you which test results they need and will help coordinate your tests before the infusion.

Before you get your Abemca® infusion, your doctor will give you chemotherapy with fludarabine and cyclophosphamide, also called lympho-depleting chemotherapy, for a few days to prepare your body before the infusion. Both are given through a tube (intravenous catheter) in your vein. The purpose of the chemotherapy is to treat your multiple myeloma. It may also help to "make room" for the new, gene modified T cells to grow. You will be asked to sign a consent form for these medicines.

## How to Prepare for Treatment

It is very important that you tell the clinic staff about any medicines you are taking during treatment. This includes prescriptions drugs, over-the-counter medicines, natural or herbal medicines, alternative medicines and vitamins.

The infusion will be scheduled by your doctor when your body is ready. This usually occurs at least 2 days after after your lympho-depleting chemotherapy has finished. Female patients will have a blood or urine test to check for pregnancy. If you become pregnant at any time after the infusion, tell your doctor right away.

Once admitted to the hospital, most patients usually stay in the hospital for at least 14 days.

To help reduce possible side effects from the infusion, we may give you a fever reducer, such as acetaminophen and an antihistamine, such as diphenhydramine about 30 to 60 minutes before your infusion. Then, your doctor will give you the Abecma® through a tube (intravenous catheter) in your vein. The infusion usually takes less than an hour.

## What to Expect During Treatment

A caregiver, relative, or friend should be with you at all times for the first 4 weeks after the infusion to monitor your well-being and to contact your doctor in case of fever or changes in your condition. Also, you should plan to stay within 1 hour of the hospital for at least 4 weeks after your Abecma® infusion.

## What to Expect After Treatment

- Do not drive, operate heavy machinery, or do other risky things for 8 weeks after your infusion. This treatment can cause temporary memory and coordination problems, sleepiness, confusion, weakness, dizziness, and seizures.
- Call your health care provider right away if you become ill. Your doctor will check to see if your treatment is working and help you with any side effects that occur. After that, you will be asked to come back to the clinic every so often for scheduled visits. You will also follow a life-long plan to monitor you for cancer.
- Side effects may happen any time within the first 8 weeks after the treatment, but some may happen later. Please tell your doctor if you have any new or uncommon symptoms. Side-effects from your treatment may include a severe flu-like syndrome that involves high fevers, chills, nausea and aches. This can also progress to trouble with breathing and difficulty getting enough oxygen, as well as very low blood pressure that can be serious and dangerous. These reactions can be mild or severe and could lead to death. If this happens, you may be admitted to the intensive care unit (ICU) for care.
- We will give you or your guardian a wallet card to carry with you. It lists all of the signs, symptoms and life-threatening events of Abecma®, including cytokine release syndrome (CRS) and neurologic toxicity that may occur. This condition requires urgent attention. You will be evaluated and admitted to the hospital right away if you develop any signs or symptoms of this condition.
- Do not donate blood, organs, tissues or cells for transplantation.