CARVYKTI™ (ciltacabtagene autoleucel) is a treatment used for adult patients who have cancer of the bone marrow called multiple myeloma. It is used when at least four other kinds of treatment have not worked or have stopped working. CARVYKTI™ is a medicine made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells.

In the treatment of relapsed or refractory multiple myeloma

IGNITE YOUR BODY'S DEFENSE WITH CARVYKTI™

What you need to know about therapy with CARVYKTI™

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about CARVYKTI™?

CARVYKTI™ may cause side effects that are severe or life-threatening and can lead to death. Call your healthcare provider or get emergency help right away if you get any of the following:

- fever (100.4°F/38°C or higher)
- chills or shaking chills
- fast or irregular heartbeat
- difficulty breathing
- very low blood pressure
- dizziness/light headedness
- effects on your nervous system, some of which can occur days or weeks after you receive the infusion, and may initially be subtle such as:
  - feeling confused, less alert or disoriented, having difficulty speaking or slurred speech, having difficulty reading, writing and understanding words, memory loss
  - loss of coordination affecting movement and balance, slower movements, changes in handwriting
  - personality changes including a reduced ability to express emotions, being less talkative, disinterest in activities, and reduced facial expression
  - tingling, numbness and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
  - facial numbness, difficulty moving muscles of face and eyes

Please click here to see full Important Safety Information.
Please click here to see full Important Product Information, including Boxed WARNINGS, and click here to see Medication Guide. Discuss any questions you have with your healthcare providers.

CARVYKTI™
(ciltacabtagene autoleucel) Suspension for IV Infusion

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and click here to see Medication Guide. Discuss any questions you have with your healthcare providers.

WHO IS CARVYKTI™ FOR?

If you're considering CARVYKTI™ (ciltacabtagene autoleucel), you've already been treated with at least four other kinds of treatment regimens, including at least one therapy from each of these drug classes: a **proteasome inhibitor**, an **immunomodulatory agent**, and an **anti-CD38 monoclonal antibody**. Either your multiple myeloma has returned or has stopped responding to treatment, and your doctor has determined that it's time to try something different.

Proteasome inhibitors include:	**Immunomodulatory drugs include:**	**Anti-CD38 monoclonal antibodies include:**
Bortezomib	Lenalidomide	Daratumumab
Carfilzomib	Thalidomide	Isatuximab
Ixazomib	Pomalidomide	

CARVYKTI™ is different than other commonly used cancer therapies (such as chemotherapy) because it is made from your own white blood cells, which are changed (genetically modified) to recognize and attack your multiple myeloma cells.

CD38=cluster of differentiation 38.
Throughout this brochure, you'll see certain **bold-typeface** words and phrases.
That means you can find a definition of each bolded term in the Glossary on pages 22-23.

GLOSSARY ›

IMPORTANT SAFETY INFORMATION

It is important that you tell your healthcare providers that you have received CARVYKTI™ and to show them your CARVYKTI™ Patient Wallet Card. Your healthcare providers may give you other medicines to treat your side effects. CARVYKTI™ can cause a very common side effect called cytokine release syndrome or CRS, which can be severe or fatal. Symptoms of CRS include fever, difficulty breathing, dizziness or lightheadedness, nausea, headache, fast heartbeat, low blood pressure, or fatigue. Tell your healthcare provider right away if you develop fever or any of these other symptoms after receiving CARVYKTI™.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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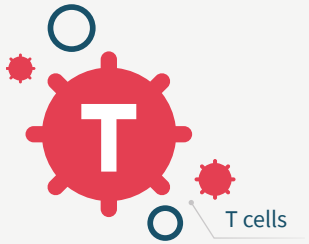
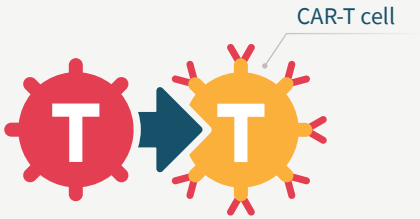
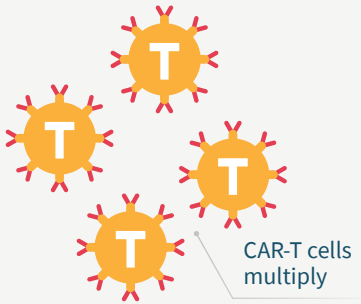
HOW CARVYKTI™ CAR-T CELL THERAPY WORKS



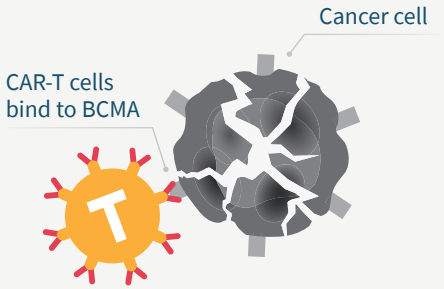
T cells are a type of immune cell that patrol the body for signs of infection and disease and then start a response to attack them. But sometimes cancer cells are structured in a way that prevents T cells from recognizing or attacking them.



CAR-T therapy works by collecting your body's own T cells and genetically modifying them to create personalized **CAR-T cells** that will recognize and fight your cancer. Your CAR-T cells are then returned to your body in a one-time infusion.



CAR-T cells will multiply in your body so that you have even more cells seeking out and destroying cancer cells.



CARVYKTI™ (ciltacabtagene autoleucel) CAR-T cells are designed to find and attack **BCMA**, a protein found on the outside of nearly all multiple myeloma cells as well as on normal plasma cells. BCMA is **over-expressed** on multiple myeloma cells.

BCMA=B cell maturation antigen; CAR-T=chimeric antigen receptor T cell.

GLOSSARY ›

IMPORTANT SAFETY INFORMATION

What should I avoid after receiving CARVYKTI™?

Do not drive, or operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get CARVYKTI™. This is because the treatment can cause memory and coordination problems, sleepiness, confusion, dizziness, seizures, or other neurologic side effects as discussed by your healthcare provider.

- You must not be given certain vaccines called live vaccines for some time before and after CARVYKTI™ treatment. Talk to your healthcare provider if you need to have any vaccinations
- Do not donate blood, organs, tissues, or cells for transplantation

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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PATIENT RESPONSES IN A CLINICAL STUDY

Ciltacabtagene autoleucel is a treatment administered in a one-time infusion that was studied in CARTITUDE-1, a clinical study of 97 adults with relapsed or refractory multiple myeloma. In the clinical study, most patients had received at least four treatment regimens, including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody before their symptoms returned or their disease stopped responding to treatment.

Overall response rate

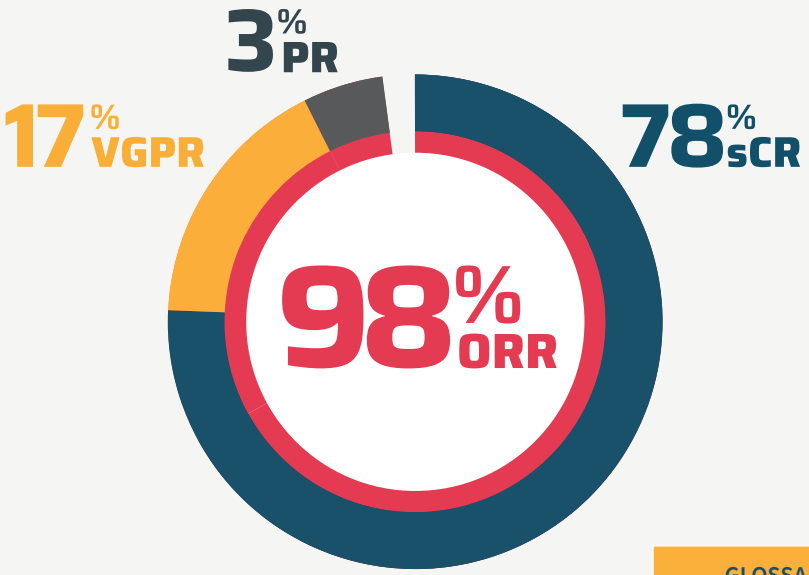
Overall response rate (ORR) is the percentage of people who have any kind of response after treatment with ciltacabtagene autoleucel. In the CARTITUDE-1 study, 95 of 97 patients responded to ciltacabtagene autoleucel for an ORR of 98%.

Types of treatment response

ORR includes people with different kinds of responses. In the CARTITUDE-1 study:

- 76 of 97 people (78%) experienced a **stringent complete response (sCR)**—the best possible response
- 16 of 97 people (17%) experienced a **very good partial response (VGPR)**
- 3 of 97 people (3%) experienced a **partial response (PR)**

CD38=cluster of differentiation 38.



GLOSSARY ›

IMPORTANT SAFETY INFORMATION

CARVYKTI™ can cause various neurologic side effects, some of which may be severe or fatal. Symptoms include but are not limited to confusion, disorientation, loss of consciousness, seizures, difficulty speaking, reading or writing, tremor, slower movements, changes in personality, depression, tingling and numbness of hands and feet, leg and arm weakness, and facial numbness.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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HOW QUICKLY MIGHT IT WORK AND HOW LONG MIGHT IT LAST?

In a clinical trial, following a one-time infusion, people experienced the following responses:

Median time to first response was 1 month

In the CARTITUDE-1 study, some people responded to ciltacabtagene autoleucel as soon as 0.9 months after infusion and some as late as 10.7 months.
The median, or amount of time where half responded sooner and half responded later, was 1 month.

Median duration of response was 21.8 months

Median duration of response (mDOR) among people who responded to treatment was 21.8 months at 18 months of median follow-up in the clinical trial. This means that in the CARTITUDE-1 study, half of the people treated kept responding to ciltacabtagene autoleucel for at least 21.8 months.

Median duration of response (mDOR) among people with stringent complete response (sCR) was not reached at 18 months of median follow-up. This means that more than half of people with sCR were still responding to treatment 18 months after being treated with ciltacabtagene autoleucel.

IMPORTANT SAFETY INFORMATION

CARVYKTI™ 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.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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SAFETY PROFILE

CARVYKTI™ (ciltacabtagene autoleucel) may cause side effects that are severe or life-threatening and can lead to death

Call your healthcare providers or get emergency help right away if you experience any of the following:

- Fever (100.4° F or 38° C or higher)
- Chills or shaking chills
- Fast or irregular heartbeat
- Difficulty breathing
- Very low blood pressure
- Dizziness or light-headedness

Call your healthcare providers or get emergency help right away if you experience effects on your nervous system, some of which can occur days or weeks after you receive the infusion, and may initially be subtle, such as:

- Feeling confused, less alert, or disoriented
- Difficulty speaking or slurred speech
- Difficulty reading, writing, and understanding words
- Memory loss
- Loss of coordination affecting movement and balance
- Slower movements
- Changes in handwriting
- Personality changes including reduced ability to express emotions, being less talkative, disinterested in activities, and reduced facial expression
- Tingling, numbness, and pain of hands and feet
- Difficulty walking, leg and/or arm weakness
- Difficulty breathing
- Facial numbness, difficulty moving face and eye muscles

It is important that you tell all of your healthcare providers that you have received CARVYKTI™. Your healthcare providers may give you other medicines to treat your side effects. You will be given a CARVYKTI™ Patient Wallet Card either before or at the time you receive your CARVYKTI™ infusion. Please carry your CARVYKTI™ Patient Wallet Card with you at all times. Show the card to any healthcare provider involved in your care and if you go to the emergency room.

See page 11 to learn more about the CARVYKTI™ Patient Wallet Card.

These are not the only side effects you should be aware of while on treatment with ciltacabtagene autoleucel. For more information, please see the Medication Guide for CARVYKTI™ or talk to your healthcare providers.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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SAFETY PROFILE (more)

Cytokine release syndrome (CRS)

CRS, including fatal or life-threatening reactions, occurred after ciltacabtagene autoleucel infusion.

CARVYKTI™ (ciltacabtagene autoleucel) can cause a very common side effect called cytokine release syndrome or CRS, which can be severe or fatal. CRS occurs when your immune system becomes overly active. This is caused by the treatment and its effect on the immune cells.

This is why it's important to share any changes in how you're feeling with your healthcare providers, regardless of how small they may seem. The members of your healthcare team are experts trained to manage CRS, and they're ready to support you.

Signs and symptoms of CRS may include:

- Fever
- Difficulty breathing
- Dizziness or light-headedness
- Nausea
- Headache
- Fast heartbeat
- Low blood pressure
- Fatigue

Tell your healthcare provider right away if you develop fever or any of these other symptoms after receiving CARVYKTI™.

In the CARTITUDE-1 study, the majority of patients (95%) experienced CRS. On average, CRS set in 7 days after infusion and lasted a median of 4 days (range was 1 to 40 days).

These are not all the possible side effects of CARVYKTI™. Tell your healthcare providers if you experience any side effects.

SAFETY PROFILE (more)

Neurologic side effects

Neurologic toxicity can be a life-threatening or even fatal condition where your central nervous system reacts to the infusion.

CARVYKTI™ (ciltacabtagene autoleucel) can cause various neurologic side effects, some of which may be severe or fatal. In the CARTITUDE-1 study, 25 people (26%) experienced neurologic toxicity. About half of these cases were serious or severe; three people died of neurologic toxicity.

Some of these neurologic toxicity events can be signs of a serious immune reaction associated with CAR-T therapy called **immune effector cell-associated neurotoxicity syndrome**, or ICANS. In the CARTITUDE-1 study, 22 people (23%) experienced ICANS. All of these people previously had CRS. Of these 22 cases, 5 were severe and 2 were fatal. The remainder (17 cases) were mild to moderate. The median time to onset of ICANS was 8 days (range, 1 to 28 days). The median duration of ICANS was 7.5 days (range, 2 to 927 days).

Other forms of neurologic toxicity that are distinct from ICANS may include **parkinsonism**, **Guillain-Barré syndrome (GBS)**, **peripheral neuropathy**, and **cranial nerve palsies**. Some people treated with ciltacabtagene autoleucel in clinical studies have experienced these other forms of neurologic toxicity. In a separate, ongoing study of ciltacabtagene autoleucel, one person died after developing GBS. Your healthcare provider will monitor for GBS and provide care as needed.

Signs or symptoms associated with neurologic toxicity, some of which may occur days or weeks following the infusion, may include:

- Confusion
- Disorientation
- Loss of consciousness
- Seizures
- Difficulty speaking, reading, or writing
- Tremor
- Slower movements
- Changes in personality
- Depression
- Tingling and numbness of hands and feet
- Leg and arm weakness
- Facial numbness

These are not all the possible side effects of CARVYKTI™. Tell your healthcare providers if you experience any side effects.

CAR-T=chimeric antigen receptor T cell; CRS=cytokine release syndrome.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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SAFETY PROFILE (more)

Common side effects

The most common side effects of CARVYKTI™ (ciltacabtagene autoleucel) include:

- Fever (100.4°F/38°C or higher), chills
- Dizziness or light-headedness
- Headache, muscle or joint pain, feeling very tired
- Altered mental state, confusion
- Infections
- Low levels of antibodies (immunoglobulins) in the blood
- Cough, being short of breath
- Diarrhea, nausea, decreased appetite, constipation
- Fast or irregular heartbeat
- Problems with blood clotting

Other possible side effects

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

CARVYKTI™ can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]) which may make you feel weak or tired, or increase your risk of severe infection or bleeding. After treatment, your healthcare providers will test your blood to check for this. Tell your healthcare providers right away if you get a fever, chills, or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

Having CARVYKTI™ in your blood may cause some commercial Human Immunodeficiency Virus (HIV) tests to incorrectly give you an HIV-positive result even though you may be HIV-negative.

These are not all the possible side effects of CARVYKTI™. Tell your healthcare providers if you experience any side effects.

SAFETY PROFILE (more)

What is the CARVYKTI™ REMS Program?

A Risk Evaluation and Mitigation Strategy (REMS) program is a drug safety program that the US Food and Drug Administration (FDA) requires for certain medicines with serious safety concerns. Drug companies and healthcare professionals must take extra steps to make sure the benefits of using the drug are more than the risks. The FDA must approve these steps as part of a REMS program.

Due to the risk of serious side effects such as cytokine release syndrome (CRS) and neurologic toxicity, which can be life-threatening and lead to death, CARVYKTI™ (ciltacabtagene autoleucel) may only be administered at healthcare facilities certified in the CARVYKTI™ REMS Program.

The CARVYKTI™ REMS Program educates patients and healthcare professionals about the major risks associated with CARVYKTI™.

As part of the CARVYKTI™ REMS Program, you will be given a CARVYKTI™ Patient Wallet Card either before or at the time of receiving your CARVYKTI™ infusion.

Work with your healthcare providers to fill out the card, and be sure to carry your completed CARVYKTI™ Patient Wallet Card with you at all times. For more information about the CARVYKTI™ REMS Program or to download a replacement card if needed, visit **CARVYKTIREMS.com**.

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CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI™ TREATMENT PROCESS

CARVYKTI™ (ciltacabtagene autoleucel) is an individualized treatment that is prescribed and infused at a Certified Treatment Center. Your primary oncologist will help you set up a consultation at a Certified Treatment Center, which will determine your eligibility and provide your treatment with CARVYKTI™. You'll still remain in contact and may keep your scheduled appointments with your primary oncologist, who will continue to be involved in your care throughout this process and especially when you return home for longer-term monitoring and follow-up care.

Therapy with CARVYKTI™ is a 5-step process that generally takes about 2 to 3 months to complete

STEP 1
Cell collection
3 to 6 hours

STEP 2
Genetically modifying your T cells
~4 weeks*

STEP 3
Pre-infusion treatment
3 days

STEP 4
One-time CARVYKTI™ infusion
30 to 60 minutes

STEP 5
Monitoring
4 weeks and beyond

Between cell collection and pre-infusion treatment, your doctor may prescribe additional therapy to treat your multiple myeloma, often called bridging therapy.†

*Timing and outcomes of manufacturing may vary.
†73/97 patients in the CARTITUDE-1 study received bridging therapy.

IMPORTANT SAFETY INFORMATION

After getting CARVYKTI™, you will be monitored at the certified healthcare facility where you received your treatment for at least 10 days after the infusion.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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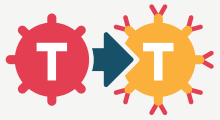
THE CARVYKTI™ TREATMENT PROCESS (more)

STEP 1 Cell collection

3 to 6 hours

Some of your blood is drawn into a machine that separates the white and red blood cells, collects some of the white blood cells (including T cells), and returns the rest of the blood into your body. This process is called **leukapheresis** (loo-kuh-fur-ee-sis). This process may take 3 to 6 hours and may need to be repeated.

STEP 2 Genetically modifying your T cells



~4 weeks*

Your white blood cells are frozen and sent to a manufacturing site, where the T cells are separated out and customized into your ciltacabtagene autoleucel CAR-T cells. This is done by genetically modifying your T cells to be able to recognize BCMA on the surface of multiple myeloma cells. Your CARVYKTI™ CAR-T cells are then frozen and sent to your CARVYKTI™ Certified Treatment Center.

Between cell collection and pre-infusion treatment, your doctor may prescribe additional therapy to treat your multiple myeloma, often called bridging therapy.†

CAR-T=chimeric antigen receptor T cell; BCMA=B cell maturation antigen.
*Timing and outcomes of manufacturing may vary.
†73/97 patients in the CARTITUDE-1 study received bridging therapy.

IMPORTANT SAFETY INFORMATION

CARVYKTI™ can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]), which may make you feel weak or tired, or increase your risk of severe infection or bleeding. After treatment, your healthcare provider will test your blood to check for this. Tell your healthcare provider right away if you get a fever, chills, or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

TIPS FOR CAREGIVERS

Continue to support the person you care for while their CAR-T cells are being manufactured, and remember that their healthcare providers are there to help every step of the way. Communicate frequently with both the person you care for and their healthcare providers, and do not hesitate to ask questions as needed.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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THE CARVYKTI™ TREATMENT PROCESS (more)

STEP 3 Pre-infusion treatment

3 days

A few days before your CARVYKTI™ infusion, you'll receive low-dose chemotherapy infusions with cyclophosphamide and fludarabine. These infusions will help prepare your body for the CAR-T infusion. Each of these infusions will be given to you once a day for 3 days. These infusions are given to help clear out some of your white blood cells to make the necessary space in your immune system for CARVYKTI™. This is also known as **lymphodepleting chemotherapy**.

Between cell collection and pre-infusion treatment, your doctor may prescribe additional therapy to treat your multiple myeloma, often called bridging therapy.*

STEP 4 One-time CARVYKTI™ infusion

30 to 60 minutes

About a month after your initial cell collection, and 2 to 4 days after your last low-dose chemotherapy, you'll be given your CARVYKTI™ through a one-time intravenous infusion that takes approximately 30 to 60 minutes. Your healthcare providers will guide you through what your infusion day will be like.

IMPORTANT SAFETY INFORMATION

Your healthcare provider will want to do blood tests to follow your progress. It is important that you have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.

CAR-T=chimeric antigen receptor T cell.
*73/97 patients in the CARTITUDE-1 study received bridging therapy.

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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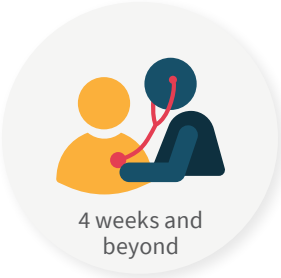
THE CARVYKTI™ TREATMENT PROCESS (more)

STEP 5 Monitoring



After your infusion of CARVYKTI™ (ciltacabtagene autoleucel), your healthcare providers at the CARVYKTI™ Certified Treatment Center will closely monitor you daily for 10 days following infusion for any signs and symptoms of a reaction to treatment.

You should plan to stay close to the location where you received your treatment for at least 4 weeks. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur. You may be hospitalized if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.

Your healthcare provider will want to do blood tests to follow your progress. It is important that you have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule. After this 4 week monitoring period, your healthcare providers will continue to provide care and partner with you to create a plan for long-term monitoring and regular follow-ups. Let your healthcare providers know if you're not feeling well. **Refrain from driving or hazardous activities for at least 8 weeks following treatment with CARVYKTI™.**

TIPS FOR CAREGIVERS

You are an extra set of eyes and ears for the healthcare providers—you can alert them quickly if any side effects occur. Be observant, and be prepared by keeping the names and phone numbers of the members of the healthcare team nearby.

IMPORTANT SAFETY INFORMATION

What should I avoid after receiving CARVYKTI™?

Do not drive, or operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get CARVYKTI™. This is because the treatment can cause memory and coordination problems, sleepiness, confusion, dizziness, seizures, or other neurologic side effects as discussed by your healthcare provider.

- You must not be given certain vaccines called live vaccines for some time before and after CARVYKTI™ treatment. Talk to your healthcare provider if you need to have any vaccinations
- Do not donate blood, organs, tissues, or cells for transplantation

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

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SUPPORT THROUGHOUT THE JOURNEY

TIPS FOR CAREGIVERS

Your role in supporting the person you care for—the encouragement, emotional support, and practical assistance you provide—makes you an important part of the treatment experience. You may need to help the person you care for with:

- Monitoring and tracking side effects
- Scheduling appointments
- Providing transportation to appointments and keeping them company
- Helping communicate with the healthcare providers (for example, providing medical and insurance information, asking questions)
- Responsibilities at home
- Emotional support and having someone to talk with
- Managing their schedule and letting visitors know when they do or don't feel up to seeing them

You don't have to manage this alone. Support is available to help you along the way, and you may want to identify friends or family who can help you as well.

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MyCARVYKTI™ PATIENT SUPPORT PROGRAM

Traveling away from home for medical care can be financially and logistically challenging. Support is available for eligible patients and their caregivers.

The MyCARVYKTI™ Patient Support Program, sponsored by Janssen Biotech, Inc., and Legend Biotech, is designed to help eligible patients prescribed CARVYKTI™ (ciltacabtagene autoleucel) and their caregivers with support during treatment.

Patients who meet financial and other eligibility requirements, and their caregivers, may receive:

- Assistance with transportation, lodging, and out-of-pocket costs related to meals and other travel expenses associated with treatment at the CARVYKTI™ Certified Treatment Center
- Support from MyCARVYKTI™ Patient Support Specialists, who are available to help guide you through the enrollment process and assist with program benefits

Learn more about MyCARVYKTI™ and find out if you're eligible

1-800-559-7875

Monday-Friday, 8:00 AM to 8:00 PM Eastern Time

CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

Please click here to see full Important Safety Information.
Please click here to see full Important Product Information, including Boxed WARNINGS, and click here to see Medication Guide. Discuss any questions you have with your healthcare providers.

QUESTIONS TO ASK YOUR HEALTHCARE PROVIDERS

While going through the treatment process, it is important to remember that your healthcare providers are there to assist you. If you have any questions about your treatment, do not hesitate to ask a member of the CARVYKTI™ Certified Treatment Center staff.

Below are examples of questions you may want to ask your healthcare providers at the certified healthcare facility.

Patient

"How will my doctor help determine whether CARVYKTI™ (ciltacabtagene autoleucel) is right for me?"

"Where do I stay while going through the process?"

"How long will this procedure/evaluation take?"

"When I'm receiving treatment with CARVYKTI™ at a Certified Treatment Center, will I be able to get up and move around?"

"What results should I expect?"

"What side effects can I expect, and how long will they last?"

"What support services are available to me?"

Caregiver

"What is my role/responsibility throughout the treatment process?"

"Who do I contact if I have questions/concerns?"

"Will I be allowed access to my loved one and their healthcare providers on a regular basis?"

"Where can I find information to help me understand the treatment process and resources?"

"What symptoms of the potential side effects should I look for?"

IMPORTANT SAFETY INFORMATION

CARVYKTI™ can cause various neurologic side effects, some of which may be severe or fatal. Symptoms include but are not limited to confusion, disorientation, loss of consciousness, seizures, difficulty speaking, reading or writing, tremor, slower movements, changes in personality, depression, tingling and numbness of hands and feet, leg and arm weakness, and facial numbness.

TIPS FOR CAREGIVERS IN CONVERSATIONS

Be an advocate for the person you care for—if they or you have questions about any aspect of treatment, ask a member of the Certified Treatment Center staff. They expect you to have lots of questions, and they understand that providing answers to your questions is an important part of a successful treatment experience.

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about CARVYKTI™?

CARVYKTI™ may cause side effects that are severe or life-threatening and can lead to death. Call your healthcare provider or get emergency help right away if you get any of the following:

- fever (100.4°F/38°C or higher)
- chills or shaking chills
- fast or irregular heartbeat
- difficulty breathing
- very low blood pressure
- dizziness/light headedness
- effects on your nervous system, some of which can occur days or weeks after you receive the infusion, and may initially be subtle such as:
  - feeling confused, less alert or disoriented, having difficulty speaking or slurred speech, having difficulty reading, writing and understanding words, memory loss
  - loss of coordination affecting movement and balance, slower movements, changes in handwriting
  - personality changes including a reduced ability to express emotions, being less talkative, disinterest in activities, and reduced facial expression
  - tingling, numbness and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
  - facial numbness, difficulty moving muscles of face and eyes

It is important that you tell your healthcare providers that you have received CARVYKTI™ and to show them your CARVYKTI™ Patient Wallet Card. Your healthcare providers may give you other medicines to treat your side effects.

How will I receive CARVYKTI™?

- CARVYKTI™ is made from your own white blood cells, so your blood will be collected by a process called “leukapheresis.” The procedure can take 3 to 6 hours and may need to be repeated
- Your white blood cells are sent to a manufacturing center to make CARVYKTI™. It takes about 4-5 weeks from the time your cells are received at the manufacturing site and are available to be shipped back to your healthcare provider, but the time may vary
- While CARVYKTI™ is being made, you may get other medicines to treat the multiple myeloma. This is so that your multiple myeloma does not get worse

Before you get CARVYKTI™, your healthcare provider will give you chemotherapy for 3 days to prepare your body.

30 to 60 minutes before you are given CARVYKTI™, you may be given other medicines. These may include:

- medicines for an allergic reaction (antihistamines)
- medicines for fever (such as acetaminophen)

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CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

IMPORTANT SAFETY INFORMATION (more)

When your CARVYKTI™ is ready, your healthcare provider will give CARVYKTI™ to you through a catheter (tube) placed into your vein (intravenous infusion). Your dose of CARVYKTI™ will be given in one infusion bag. The infusion usually takes approximately 30-60 minutes.

After getting CARVYKTI™, you will be monitored at the certified healthcare facility where you received your treatment for at least 10 days after the infusion.

You should plan to stay close to the location where you received your treatment for at least 4 weeks. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur. You may be hospitalized if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.

Your healthcare provider will want to do blood tests to follow your progress. It is important that you have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.

What should I avoid after receiving CARVYKTI™?

Do not drive, or operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get CARVYKTI™. This is because the treatment can cause memory and coordination problems, sleepiness, confusion, dizziness, seizures, or other neurologic side effects as discussed by your healthcare provider.

- You must not be given certain vaccines called live vaccines for some time before and after CARVYKTI™ treatment. Talk to your healthcare provider if you need to have any vaccinations
- Do not donate blood, organs, tissues, or cells for transplantation

What are the possible or reasonably likely side effects of CARVYKTI™?

The most common side effects of CARVYKTI™ include:

- fever (100.4°F/38°C or higher), chills
- dizziness or light-headedness
- headache, muscle or joint pain, feeling very tired
- altered mental state, confusion
- infections
- low levels of antibodies (immunoglobulins) in the blood
- cough, being short of breath
- diarrhea, nausea, decreased appetite, constipation
- fast or irregular heartbeat
- problems with blood clotting

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CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

IMPORTANT SAFETY INFORMATION (more)

CARVYKTI™ can cause a very common side effect called cytokine release syndrome or CRS, which can be severe or fatal. Symptoms of CRS include fever, difficulty breathing, dizziness or lightheadedness, nausea, headache, fast heartbeat, low blood pressure, or fatigue. Tell your healthcare provider right away if you develop fever or any of these other symptoms after receiving CARVYKTI™.

CARVYKTI™ 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.

CARVYKTI™ can cause various neurologic side effects, some of which may be severe or fatal. Symptoms include but are not limited to confusion, disorientation, loss of consciousness, seizures, difficulty speaking, reading or writing, tremor, slower movements, changes in personality, depression, tingling and numbness of hands and feet, leg and arm weakness, and facial numbness.

CARVYKTI™ can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]), which may make you feel weak or tired, or increase your risk of severe infection or bleeding. After treatment, your healthcare provider will test your blood to check for this. Tell your healthcare provider right away if you get a fever, chills, or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

Having CARVYKTI™ in your blood may cause some commercial Human immunodeficiency virus (HIV) tests to incorrectly give you an HIV-positive result even though you may be HIV-negative.

These are not all the possible side effects of CARVYKTI™. Call your healthcare provider if you have any side effect.

You may report side effects to FDA at 1-800-FDA-1088.

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CARVYKTI™ (ciltacabtagene autoleucel) Suspension for IV Infusion

GLOSSARY

Below you will find definitions for terms related to CAR-T therapy with CARVYKTI™ (ciltacabtagene autoleucel) that may be unfamiliar to you.

B cell maturation antigen (BCMA)—a kind of marker that is found on the surface of myeloma cells and some types of immune cells.

CAR-T cells—T cells that have been genetically modified in a laboratory to effectively identify targets on cancer cells in order to bind to and destroy them.

CAR-T therapy—a cancer treatment in which your T cells are collected and then genetically modified to create customized CAR-T cells that will fight your cancer. These CAR-T cells are then returned to your body in a one-time infusion.

Cranial nerve palsy—paralysis of the nerves that send information between the brain and the sense organs (the eyes, ears, nose, and tongue). They also send information to the muscles in the face, head, neck, and other organs in the body, including the larynx (voice box), heart, lungs, stomach, and intestines.

Cytokine release syndrome (CRS)—a condition that can occur after some types of immunotherapy treatment such as treatment with monoclonal and CAR-T cell infusions. CRS is caused by the rapid release of cytokines into the blood from immune cells affected by the immunotherapy. Cytokines are immune substances that have many different purposes in the body. Most patients have a mild reaction, but sometimes the reaction may be severe or life-threatening.

Guillain-Barré syndrome (GBS)—a rare condition in which the body's immune system attacks the nerves located outside the brain and spinal cord. Symptoms include muscle weakness, muscle pain, numbness, and tingling. Other symptoms may include problems with vision, speech, swallowing, digestion, and bladder control.

Immune effector cell-associated neurotoxicity syndrome (ICANS)—a clinical and neuropsychiatric syndrome that can occur in the days to weeks following administration of certain types of immunotherapy, especially immune effector cell (IEC) and T cell engaging therapies.

Leukapheresis—the first step of the CARVYKTI™ treatment process. In this step, your blood is drawn and passed through a machine that collects some of your blood, separates out some of your white blood cells, and then returns the rest of the blood to your body. This process takes 3-6 hours. The collected T cells are then sent to a manufacturing lab where they will be used to make your unique CAR-T cells.

Lymphodepleting chemotherapy—a step in the CARVYKTI™ treatment process that takes place a few days before your infusion. To prepare your body to receive CARVYKTI™, you are given infusions of low-dose chemotherapy once a day for 3 consecutive days. This treatment reduces the number of white blood cells in your body, giving the CARVYKTI™ CAR-T cells room to multiply once they are returned to your body.

Median duration of response (mDOR)—the length of time where half the patients in a group had longer responses to a drug and half had shorter responses. If the mDOR is not reached by a certain time point, that means that more than half of the patients are still experiencing a response—which means the drug is still working to fight their cancer.

GLOSSARY (more)

Below you will find definitions for terms related to CAR-T therapy with CARVYKTI™ (ciltacabtagene autoleucel) that may be unfamiliar to you.

Neurologic toxicity—occurs when the exposure to toxic substances alters the normal activity of the nervous system. This can eventually disrupt neurons (key cells that transmit and process signals in the brain and other parts of the nervous system). Neurologic toxicity can result from exposure to substances used in chemotherapy, radiation treatment, drug therapies, and organ transplants, or exposure to other substances. Individuals with certain disorders may be especially vulnerable to substances that can cause neurologic toxicity.

Overall response rate (ORR)—the percentage of people whose disease was reduced after treatment.

Overexpression—when a marker or protein expressed by several types of cells is more highly expressed by one type of cell. For example, B cell maturation antigen (BCMA) is overexpressed on myeloma cells compared with healthy plasma cells.

Parkinsonism—refers to symptoms of Parkinson disease, including slow movements and tremors that are caused by another condition or certain drugs and toxins.

Partial response (PR)—a positive but incomplete result of treatment with a drug, where certain laboratory measurements of disease are reduced somewhat, but not enough to meet the standard of very good partial response (VGPR) or stringent complete response (sCR).

CAR-T=chimeric antigen receptor T cell; CD38=cluster of differentiation 38.

Peripheral neuropathy—a nerve problem that can cause pain, numbness, tingling, swelling, or muscle weakness in different parts of the body. It is frequently caused by cancer or cancer treatments, such as chemotherapy.

Proteasome inhibitors, immunomodulatory drugs, and anti-CD38 monoclonal antibodies—three different forms of treatment for multiple myeloma that patients receive prior to being eligible for CAR-T therapy with CARVYKTI™.

Proteasome inhibitors	**Immunomodulatory drugs**	**Anti-CD38 monoclonal antibodies**
Bortezomib	Lenalidomide	Daratumumab
Carfilzomib	Thalidomide	Isatuximab
Ixazomib	Pomalidomide	

Stringent complete response (sCR)—a positive result of treatment with a drug, in which the doctor is unable to observe any signs or symptoms of the disease via imaging or other specific blood and bone marrow tests after treatment.

T cells—a type of immune cell that patrols the body for signs of infection and diseases, and initiates a response to attack both.

Very good partial response (VGPR)—a positive result of treatment with a drug, where one laboratory measurement of disease is almost eliminated, but not by enough to meet the standard of sCR.

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