

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.

CARING FOR SOMEONE AFTER A CARVYKTI® INFUSION

Your important role
in post-infusion
monitoring



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/lightheadedness
- 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 read full Important Safety Information. Please [click here](#) to read full Prescribing Information, including Boxed Warning, and [click here](#) to read Medication Guide. Discuss any questions you have with your healthcare team.



HOW YOU CAN SUPPORT SOMEONE POST-INFUSION

This guide is provided to help you as a caregiver, and any other care partners who may be involved, be prepared to care for someone after they receive a CARVYKTI® (ciltacabtagene autoleucel) infusion. The recovery phase after the infusion is a crucial time, and your role as a caregiver will be to help the person you are caring for as they go through the recovery experience after they leave the care of the certified healthcare facility where they received CARVYKTI®.

It's normal to feel nervous or overwhelmed about what is expected of you. **You and your care partners can make all the difference in the world for the person you are caring for—with your time, encouragement, and practical support.**

Understanding what signs and symptoms of side effects to look for, and notifying the healthcare team as soon as you see one, is an important responsibility of caregivers, as well as:

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)

Assisting with responsibilities at home

Providing emotional support and giving them someone to talk with

Managing their schedule and coordinating time for friends and family to visit

Coordinating care with other care partners to ensure someone is always available for the person you are caring for



PROVIDING ENCOURAGEMENT

Treating multiple myeloma can be challenging. You can help the person you are caring for with some of the daily struggles, such as eating right or talking through their emotions.

There's no way to anticipate everything you'll need to know as a caregiver, but by becoming familiar with the disease and treatment, you can offer support to help the person you care for make informed decisions.

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®.

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SHORT-TERM MONITORING AFTER THE ONE-TIME CARVYKTI® INFUSION

After the person you are caring for has received the one-time CARVYKTI® (ciltacabtagene autoleucel) infusion, they will continue to be monitored at the certified healthcare facility where they received the infusion. The healthcare team will check to see that treatment is working and manage any side effects that may occur. Serious side effects may require hospitalization until the side effects are under control and it is safe to leave the hospital.

WHAT TO EXPECT AFTER INFUSION



Daily monitoring for 10 days at the certified healthcare facility

The person you are caring for will receive daily monitoring for side effects at the certified healthcare facility for at least 10 days after the infusion. The healthcare team will manage any side effects that may occur.



Stay close to the certified healthcare facility for at least 4 weeks

You and the person you are caring for will stay within proximity of the certified healthcare facility for at least 4 weeks. The healthcare team will check to see that the treatment is working for the person you are caring for and will help manage any side effects that may occur.



CONTACT THE HEALTHCARE TEAM IMMEDIATELY IF YOU THINK YOU ARE SEEING SIGNS OR SYMPTOMS OF A SIDE EFFECT

As the caregiver, you may be the first to notice subtle changes in the person you care for. If you notice any of the signs or symptoms listed on the next page, or if they think they are having any other signs of side effects, contact their healthcare provider or the certified healthcare facility right away.

IMPORTANT SAFETY INFORMATION (more)

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

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SHORT-TERM MONITORING AFTER THE ONE-TIME CARVYKTI® INFUSION (more)

AS A CAREGIVER, BE AWARE OF CERTAIN SIGNS AND SYMPTOMS OF SIDE EFFECTS THAT COULD OCCUR

Signs and symptoms of cytokine release syndrome may include:				
• Fever	• Fatigue	• Nausea	• Headache	• Fast heartbeat
• Difficulty breathing	• Low blood pressure	• Dizziness or lightheadedness		
Signs and symptoms of life-threatening infections may include:				
• Fever	• Chills	• Any sign of infection		
Signs and symptoms associated with neurologic side effects, some of which may occur days or weeks following the infusion, may include:				
• Confusion	• Disorientation	• Loss of consciousness	• Seizures	• Leg and arm weakness
• Tremor	• Slower movements	• Changes in personality	• Depression	• Facial numbness
• Difficulty speaking, reading, or writing		• Tingling and numbness of hands and feet		
Signs and symptoms associated with cytopenias (low blood counts) may include:				
• Feeling tired	• Weakness	• Shortness of breath	• Any sign of infection	• Fever
• Bleeding and bruising	• Chills			

Regardless of how small it may seem, it's important to share with the healthcare team any side effects that develop. Some side effects can be serious, even life-threatening, and need to be identified and treated quickly. These are not all the side effects that can occur. Please refer to the [Medication Guide](#) for an extensive list of signs and symptoms to watch for.

MONITORING FOR SYMPTOMS OF NEUROLOGIC SIDE EFFECTS

Always alert the healthcare team if you recognize any changes in the person you care for, so the team can assess the patient as quickly as possible. One of these assessments may include the ICE test, which can help detect a neurologic side effect called ICANS. The ICE test includes asking the person you care for to answer simple questions and perform certain exercises, such as:

1. **Orientation:** Recalling what month and year it is.
2. **Naming:** Pointing to certain objects in the room.
3. **Following commands:** "Show me 2 fingers."
4. **Writing:** Ability to write a standard sentence.
5. **Attention:** "Can you count backwards from 100 by tens?"

ICANS=immune effector cell-associated neurotoxicity syndrome; ICE=immune effector cell-associated encephalopathy.

IMPORTANT SAFETY INFORMATION (more)

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.

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LONG-TERM CARE AND MONITORING

After the initial 4-week monitoring period at or near the certified healthcare facility, your healthcare team will determine when you and the person you are caring for may return home. When this happens, the primary oncology team will continue to provide care and partner with you to create a plan for long-term monitoring and regular follow-up visits.

KEEP THESE ADDITIONAL GUIDELINES IN MIND FOR LONG-TERM CARE

- ☐ **Keep monitoring**
Continue monitoring for signs and symptoms of side effects. Side effects may develop even after you and the person you care for have returned home.
- ☐ **Secure a driver**
Ensure the person you care for has a driver to take them to all appointments and other places requiring travel. The person you care for must refrain from driving or hazardous activities for at least 8 weeks following infusion.
- ☐ **Schedule ahead**
Make sure all of the important appointments with the primary oncologist are scheduled and ensure that you or another care partner is able to attend those visits.

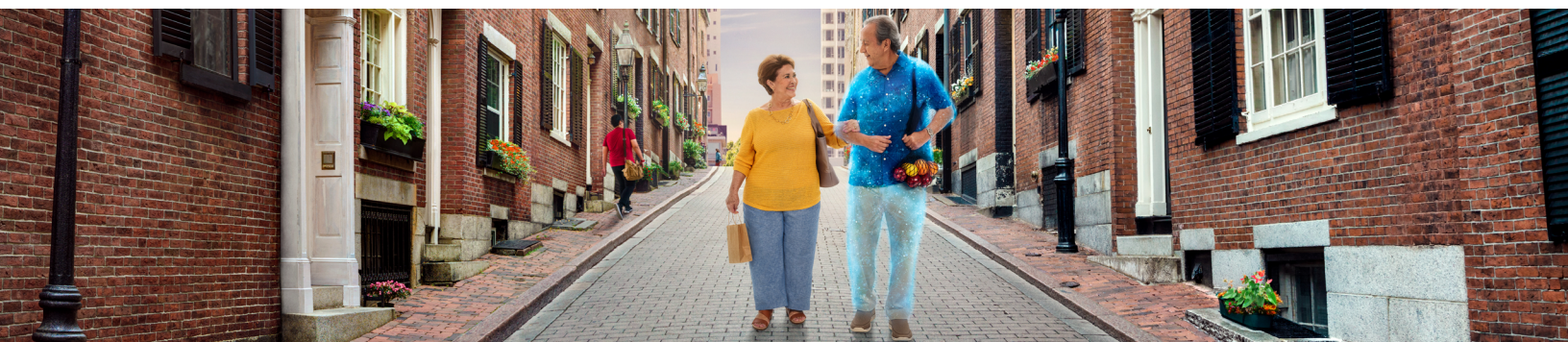


WATCHING OUT FOR SIDE EFFECTS

You are an extra set of eyes and ears for the healthcare providers. As someone who knows the person you are caring for better than the healthcare providers, you may notice changes in behavior, personality, or handwriting sooner than they do. Alert the healthcare team quickly if you notice any signs or symptoms or you think the person you are caring for is having a side effect. Be observant and be prepared by keeping the names and phone numbers of the healthcare team nearby in the event you have any questions or a side effect occurs.



Visit [CARVYKTI.com](https://carvykti.com) to find more resources and support for you, including a guide to help monitor for side effects.



IMPORTANT SAFETY INFORMATION (more)

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 that may lead to death. 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.

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TAKING CARE OF YOUR OWN NEEDS

Caring for someone with multiple myeloma is time consuming. It's easy to get so immersed in caring for them that you neglect your own physical, mental, and emotional health. This can lead to burnout. That's why it's so important to pay attention to your well-being. Your needs as a caregiver are distinct from the needs of the person you are caring for. These tips can help you stay focused on giving the long-term support that is needed.

TAKE TIME FOR YOURSELF

Carve out time specifically for resting and doing things you enjoy. Some ideas include:

Napping

Eating a fresh, healthy meal

Exercising or doing yoga

Keeping up with a hobby

Taking a drive

Seeing a movie

Working in the yard

Going shopping

Catching up on phone calls, letters, or email

Journaling or meditating



DON'T GO IT ALONE, IF POSSIBLE

It's good to have help with caregiving responsibilities, but having consistent support for your needs is also important. Consider finding a support group or talking to a counselor. You can ask your healthcare facility for support and resources that may be available through the hospital, or refer to the list of support and advocacy groups for caregivers at [CARVYKTI.com](https://www.carvykti.com).



ALMOST HALF OF CAREGIVERS FOR SOMEONE WITH MULTIPLE MYELOMA SUFFER FROM ANXIETY

Your circumstances will be unique to you, but there are many reasons why you may experience symptoms of anxiety. These can include managing medical needs, navigating the healthcare system, fears about disease relapse, financial or work-related concerns, navigating shifts in your relationships, or even changes in intimacy. You are not alone in facing these challenges, and it is not a sign of failure if you need help or need to take care of yourself.

IMPORTANT SAFETY INFORMATION (more)

CARVYKTI® can increase the risk of life-threatening infections including COVID-19 that may lead to death. Tell your healthcare provider right away if you develop fever, chills, or any signs or symptoms of an infection.

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DEFINITIONS OF SIDE EFFECTS

Always feel free to ask your healthcare team to define a term if it is unfamiliar to you or the person you are caring for. The terms below are some common side effects. Alert the healthcare team quickly if any side effects occur.

To learn more about side effects, download the [Monitoring for Potential Side Effects Guide](#) brochure.

Cranial nerve palsies—partial weakness or complete paralysis of the areas served by 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 antibodies 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.

Cytopenia—a condition in which there is a lower-than-normal number of blood cells.

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.

Hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS)—a rare disorder in which various types of white blood cells build up in organs, including the skin, spleen, and liver, and destroy other blood cells, possibly leading to organ failure.

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 and T cell-engaging therapies.

Immune mediated myelitis—immune mediated inflammatory diseases (IMIDs) is an umbrella term that encompasses a number of common, chronic and complex disorders, characterized by a dysregulation or abnormality of the normal immune response which leads to inflammation in target organs and, usually, systemic effects as well. Myelitis refers to inflammation of the spinal cord. It can damage the insulating material, called myelin, that covers nerve cell fibers.

Hypogammaglobulinemia—a condition in which the level of antibodies in the blood is low and the risk of infection is high.

Neurologic side effects—occur 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 side effects 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 side effects.

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

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



BEING AN ADVOCATE

It's important to be an advocate for the person you care for. If they or you have questions about any part of treatment, ask a member of the certified healthcare facility 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.

IMPORTANT SAFETY INFORMATION (more)

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.

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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/lightheadedness
- 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)

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.

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IMPORTANT SAFETY INFORMATION (more)

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 lightheadedness
- 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

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 including COVID-19 that may lead to death. Tell your healthcare provider right away if you develop fever, chills, or any signs or symptoms of an infection.

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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 that may lead to death. 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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