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 one other treatment has not worked or has 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.

For Patients and Care Partners

CARVYKTI® TREATMENT GUIDEBOOK

Important milestones during your CARVYKTI® treatment journey

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 read full Important Safety Information.
Please read full Prescribing Information, including Boxed Warning, and read the Medication Guide.
Discuss any questions you have with your healthcare team.

CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

WELCOME TO YOUR CARVYKTI® TREATMENT JOURNEY

You've taken a big step in moving forward with your CARVYKTI® treatment plan.

To help guide you and your care partner through your treatment with CARVYKTI® (ciltacabtagene autoleucel), **this guidebook contains information about the treatment as well as resources to assist you with questions about the process.** You may want to bring this guidebook with you to appointments, and refer to it throughout your treatment.

This guidebook should not replace the advice and guidance from your healthcare team. If you have questions or would like more detailed information about your treatment, always contact your healthcare team.

You should rely on your care partner and your healthcare team for support throughout your journey.

You can use this guidebook to:

Track your progress through the treatment process

Capture your thoughts and feelings

Record your appointments and healthcare team contact information

Note how you're feeling or any symptoms you may experience

Share your notes and questions with your healthcare team throughout your journey

IMPORTANT SAFETY INFORMATION (cont)

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.

Please read full Important Safety Information.
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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

CARVYKTI® AND YOU

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 one other treatment has not worked or has stopped working. **CARVYKTI® is made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells. Because of the way it works, it may affect certain normal healthy cells too.**

Ciltacabtagene autoleucel is a treatment administered in a one-time infusion that was studied in CARTITUDE-4, a clinical study of 419 adults with relapsed or refractory multiple myeloma. In the clinical study, patients had received at least one treatment regimen that included a proteasome inhibitor and an immunomodulatory agent, and had not responded to lenalidomide, before their symptoms returned or their disease stopped responding to treatment.

Your doctor has prescribed CARVYKTI® because they feel that the potential benefits to you outweigh the risks.

CARVYKTI® modifies your immune system, which can cause side effects. Some of these side effects can be serious or life-threatening. Contact your healthcare team if you think you are experiencing any side effects at any point in your treatment journey, especially after you receive your CARVYKTI® infusion. Ask your healthcare team if there are any particular signs or symptoms you should watch out for at each treatment step.

CARVYKTI® treatment is available only at CARVYKTI® Certified Treatment Centers. These are Certified Treatment Centers where doctors and nurses can prepare you for CAR-T therapy, administer CARVYKTI®, and mitigate potential side effects.

The healthcare team at your Certified Treatment Center will partner with your primary oncologist to coordinate your ongoing care following treatment.

WHAT IS THE CARVYKTI® REMS PROGRAM?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. 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 outweigh the risks. The FDA requires these steps as part of a REMS Program.

Due to the risk of cytokine release syndrome and neurologic toxicity, both of which can be life-threatening and can lead to death, CARVYKTI® may only be administered at healthcare settings certified in the CARVYKTI® REMS Program.

The goal of the CARVYKTI® REMS is to mitigate the risks of cytokine release syndrome (CRS) and neurologic toxicities.

For more information about the CARVYKTI® REMS Program visit CARVYKTIrems.com.

CAR-T=chimeric antigen receptor-T cell.

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

If you have any questions about your treatment, ask a member of your CARVYKTI® (ciltacabtagene autoleucel) healthcare team.

Use this space to write down questions as they occur to you. You can use these notes to remind yourself to ask your healthcare team at your next appointment.

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IMPORTANT SAFETY INFORMATION (cont)

Before you receive CARVYKTI® tell your healthcare provider about all your medical conditions, including if you have:

- Current or past neurologic problems (such as seizures, stroke, new or worsening memory loss)
- Lung or breathing problems
- Heart problems
- Liver problems
- Kidney problems
- A recent or active infection
- Low blood counts

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

CARVYKTI® (ciltacabtagene autoleucel) is an individualized treatment and requires a specialized healthcare team. Your primary oncologist will help you set up a consultation at a CARVYKTI® Certified Treatment Center where you'll meet with a healthcare team who will determine your eligibility for treatment. 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 TO 5 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.†

For more information on what to expect at each stage of your CARVYKTI® journey, **click here** to watch the CARVYKTI® Treatment Process video.

*Timing and outcomes of manufacturing may vary.
†208/208 patients in the CARTITUDE-4 study received bridging therapy.

Sign up for updates
Get additional tips and information tailored to each stage in your journey.

Sign up for updates at **CARVYKTI.com/sign-up-for-updates**

IMPORTANT SAFETY INFORMATION (cont)

In a study comparing CARVYKTI® to standard therapy, there was a higher rate of death in the first 10 months in the CARVYKTI® arm (14%) compared to the standard therapy arm (12%). The increased rate of deaths occurred before receiving CARVYKTI® and after treatment with CARVYKTI®. The reasons for death were progression of multiple myeloma and side effects of the treatment.

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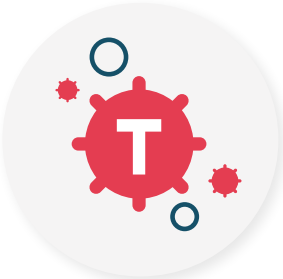
Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 1 Cell collection



Some of your blood is drawn into a machine that separates the white and red blood cells, then it collects some of the white blood cells (including T cells), and returns the rest of the blood back into your body. This process is called **'leukapheresis'** (loo-kuh-fur-ee-sis). This process may take ~3-6 hours, and may need to be repeated.

TIPS FOR CARE PARTNERS THROUGHOUT TREATMENT

Your role in supporting the person you care for—the time, energy, and attention you provide—can be critical. You can provide encouragement and emotional support, and help with daily tasks.

Questions to consider asking your healthcare team in preparation for cell collection:

- How should I prepare?
- Is there any part of my medical history or background I need to share?
- Do I need to make any changes in my diet or in the other medications or herbal or vitamin supplements that I take?
- Where do I stay while going through this process?
- Are there any signs or symptoms of side effects associated with this procedure?
- Will I need to undergo leukapheresis again?

IMPORTANT SAFETY INFORMATION (cont)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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' (loo-kah-fur-ee-sis). 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®.

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 1 Cell collection

- What is my care partner's role in this step?
- Who should my care partner contact if they have questions or concerns?
- Will my care partner be able to stay with me during this step?

IMPORTANT SAFETY INFORMATION (cont)

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.

HOW TO GET READY FOR YOUR VISIT

It is generally recommended that a care partner or travel partner accompany you to your visit. Please discuss with your healthcare team if there are any special requirements that apply to your personal circumstances.

Also, consider avoiding caffeinated beverages such as coffee, tea, and soda before your appointment. Wearing comfortable, loose-fitting clothing, as well as long pants and closed shoes with socks, may help keep you warm, and a short-sleeve shirt will allow the leukapheresis team to access the veins in your arms.

CARE PARTNER TIPS

- Help plan the trip to and from the CARVYKTI® Certified Treatment Center
- Suggest the person you're caring for has activities to keep them occupied during the cell collection procedure (for example, books and their cell phone)
- Double-check the appointment time and plan travel accordingly

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

Use this space to write down key information, as well as any thoughts, feelings, or reactions you have during this step of the treatment process.

STEP 1 Cell collection

Date of treatment

Name/address of the CARVYKTI® Certified Treatment Center

Phone number of the CARVYKTI® Certified Treatment Center and/or nurse

Medications and supplements you're currently taking

Pre-cell collection instructions or reminders

Cell collection instructions or reminders

Post-cell collection instructions or reminders

THE CARVYKTI® TREATMENT PROCESS

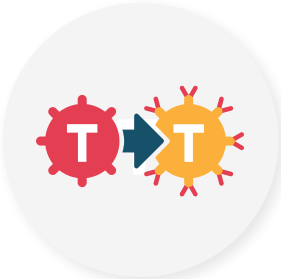
STEP 1 Cell collection

Notes

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 2 Genetically modifying your T cells



Your white blood cells are frozen and sent to a manufacturing site, where the T cells are separated out and customized into your CARVYKTI® 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.**

BCMA=B cell maturation antigen; CAR-T=chimeric antigen receptor-T cell.
*73/97 patients in the CARTITUDE-4 study received bridging therapy.

Questions to ask your healthcare team:

- Is there anything I should or should not be doing while my CARVYKTI® CAR-T cells are being manufactured?
- Do I need to make any changes in my diet or in the other medications or herbal or vitamin supplements that I take?
- Will I be receiving bridging therapy during this time? If so, where will I receive bridging therapy?
- Will my healthcare team be contacting me during this period?
- How will I know when my CARVYKTI® CAR-T cells are ready?

IMPORTANT SAFETY INFORMATION (cont)

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.

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.

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 2 Genetically modifying your T cells

- What does my care partner need to do to help me during this step?

- Who should my care partner contact if they have questions or concerns?

CARE PARTNER TIPS

Focus on continuing to support the person you care for while their CAR-T cells are being manufactured, and remember that their healthcare team is there to help every step of the way. This can be a stressful time, so additional emotional support may be needed during this waiting period. It's also recommended that you accompany the one you care for to their bridging therapy appointments, if permitted by the healthcare team.

Communicate frequently with both the person you care for and their healthcare team, and do not hesitate to ask questions as needed.

CAR-T=chimeric antigen receptor-T cell.

Notes

THE CARVYKTI® TREATMENT PROCESS

Use this space to write down key information, as well as any thoughts, feelings, or reactions you have during this step of the treatment process.

STEP 2 Genetically modifying your T cells

Name/address of the CARVYKTI® Certified Treatment Center

Phone number of the CARVYKTI® Certified Treatment Center and/or nurse

Bridging therapy treatment and appointments, if your healthcare team prescribes it

Notes

Please read full Important Safety Information.
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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 2 Genetically modifying your T cells

Notes

THE CARVYKTI® TREATMENT PROCESS

STEP 3 Pre-infusion treatment

A few days before your CARVYKTI® (ciltacabtagene autoleucel) infusion, you'll receive low-dose chemotherapy infusions with cyclophosphamide and fludarabine. These infusions will help prepare your body for the 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**.

IMPORTANT SAFETY INFORMATION (cont)

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.

Questions to ask your healthcare team:

- Where will I receive low-dose chemotherapy infusions?
- How should I prepare?
- How long will these visits be?
- Do I need to make any changes in my diet or in the other medications or herbal or vitamin supplements that I take?
- Where do I stay while going through this process?
- Are there any signs or symptoms of side effects associated with this low-dose chemotherapy?
- If I am hospitalized, can care partners visit or stay with me?

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 3 Pre-infusion treatment

- What is my care partner's role in this step?
- Who should my care partner contact if they have any questions or concerns?
- Will my care partner be able to stay with me during this step?
- What symptoms should my care partner watch out for and what should they do if they identify any signs or symptoms of side effects?

Notes

IMPORTANT SAFETY INFORMATION (cont)

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.

CARE PARTNER TIPS

- Help plan the trip to and from the CARVYKTI® Certified Treatment Center
- Suggest the person you're caring for has activities to keep them occupied during the pre-infusion treatment (for example, books and cell phone)
- Double-check the appointment time and plan travel accordingly
- Talk to the healthcare team for tips and advice for what to do before and after each infusion

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

Use this space to write down key information, as well as any thoughts, feelings, or reactions you have during this step of the treatment process.

STEP 3 Pre-infusion treatment

Dates of treatment

Name/address of the CARVYKTI® Certified Treatment Center

Phone number of the CARVYKTI® Certified Treatment Center and/or nurse

Pre-treatment instructions or reminders

Treatment instructions or reminders

Post-treatment instructions or reminders

Notes

Please read full Important Safety Information.
Please read full Prescribing Information, including Boxed Warning, and read the Medication Guide.
Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 3 Pre-infusion treatment

Notes

THE CARVYKTI® TREATMENT PROCESS

STEP 4 One-time CARVYKTI® infusion

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

CARVYKTI® is an individualized treatment that is prescribed and infused at a Certified Treatment Center.

IMPORTANT SAFETY INFORMATION (cont)

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

Questions to ask your healthcare team:

- Where will my CARVYKTI® infusion be performed? Will I have to lie down, or can I sit in a chair to have my infusion?
- Is there anything specific I should pack to bring with me? Is it possible to bring books/iPad and other forms of entertainment?
- Can I bring food/drinks?
- Can my care partners or travel partner stay with me during my CARVYKTI® infusion?
- Where will the infusion take place?
- Who will administer the treatment?

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 4 One-time CARVYKTI® infusion

- What is my care partner's role in this step?
- Who should my care partner contact if they have any questions or concerns?
- Will my care partner be able to stay with me during this step?
- Should my care partner and I plan to stay near the CARVYKTI® Certified Treatment Center?

Notes

CARE PARTNER TIPS

- Help plan the trip to and from the Certified Treatment Center
- Suggest the person you are caring for has activities to stay occupied during the procedure (books, cell phone)
- Double-check the appointment time and plan travel accordingly
- Talk to the healthcare team for tips and advice for what to do before and after the infusion

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Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

Use this space to write down key information, as well as any thoughts, feelings, or reactions you have during this step of the treatment process.

STEP 4 One-time CARVYKTI® infusion

Date of CARVYKTI® (ciltacabtagene autoleucel) infusion

Name/address of the CARVYKTI® Certified Treatment Center

Phone number of the Certified Treatment Center and/or nurse

Pre-infusion instructions or reminders

Instructions or reminders for receiving CARVYKTI®

Post-infusion instructions or reminders

Notes

Please read full Important Safety Information.
Please read full Prescribing Information, including Boxed Warning, and read the Medication Guide.
Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

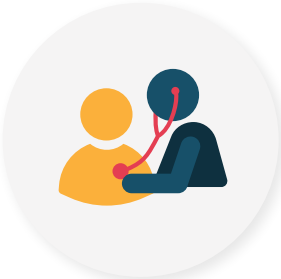
THE CARVYKTI® TREATMENT PROCESS

STEP 4 One-time CARVYKTI® infusion

Notes

THE CARVYKTI® TREATMENT PROCESS

STEP 5 Monitoring



After your infusion of CARVYKTI® (ciltacabtagene autoleucel), your healthcare team 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 team 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 team 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 team as soon as possible to reschedule.

After this 4-week monitoring period, your healthcare provider will continue to provide care and partner with you to create a plan for long-term monitoring and regular follow-ups. Let your healthcare provider know if you're not feeling well. **Refrain from driving or hazardous activities for at least 8 weeks following treatment with CARVYKTI®.**

Report signs and symptoms of side effects immediately

Any signs and symptoms of side effects should be reported to your CAR-T healthcare team as soon as possible. Your healthcare team may also ask you to perform certain tests to determine whether you're experiencing particular side effects. These tests may be blood tests, or questions or actions that you answer or perform with your healthcare team.

CAR-T=chimeric antigen receptor-T cell.

IMPORTANT SAFETY INFORMATION (cont)

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.

Please read full Important Safety Information.
Please read full Prescribing Information, including Boxed Warning, and read the Medication Guide.
Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 5 Monitoring

What is the most important information I should know about CARVYKTI® (ciltacabtagene autoleucel)?

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 or 38°C or higher)
- Chills or shaking chills
- Fast or irregular heartbeat
- Difficulty breathing
- Very low blood pressure
- Dizziness or 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

These are not all the side effects associated with CARVYKTI®.

For further details on monitoring after your CARVYKTI® infusion, click this box to download the *CARVYKTI® Monitoring for Potential Side Effects brochure*.

IMPORTANT SAFETY INFORMATION (cont)

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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Please read full Prescribing Information, including Boxed Warning, and read the Medication Guide.
Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

STEP 5 Monitoring

Monitoring for neurologic toxicity with the ICE assessment tool

An important assessment tool your healthcare team may perform

Your healthcare team may occasionally use something called the ICE assessment tool to read whether you're experiencing certain neurological side effects. The ICE assessment tool consists of several simple questions or directions for you to respond to.

Your healthcare team will use the ICE assessment tool to help detect and measure a type of neurologic toxicity called immune effector cell–associated neurotoxicity syndrome, or ICANS. If they do detect signs or symptoms of ICANS, they may perform additional tests to see if you need treatment.

ICE assessment tool=immune effector cell–associated encephalopathy assessment tool.

IMPORTANT SAFETY INFORMATION (cont)

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.

CARVYKTI® may increase your risk of getting cancers including certain types of blood cancers. Your healthcare provider should monitor you for this.

The ICE assessment tool includes questions to answer and directions to follow

Orientation
Tell your nurse or doctor what month and year it is, and which city and hospital you are in.

Naming
Identify 3 objects that your nurse or doctor points to.

Following commands
Follow simple directions your nurse or doctor gives you (for example, hold up 2 fingers).

Writing
Write down a simple sentence that your nurse or doctor says to you.

Attention
Count backwards from 100 by tens.

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THE CARVYKTI® TREATMENT PROCESS

STEP 5 Monitoring

Questions to ask your healthcare team:

- What are potential serious or common signs or symptoms of side effects?
- When are side effects expected to occur? How do I look for symptoms? How will I recognize if I have symptoms?
- How long can potential side effects last after receiving CARVYKTI® (ciltacabtagene autoleucel)?
- How long do I need to stay at or near the CARVYKTI® Certified Treatment Center after receiving CARVYKTI®?
- If I'm staying near the CARVYKTI® Certified Treatment Center, do I need to arrange for my own transportation back and forth?
- When will I be able to return home?
- What are my activity restrictions?
- What is my monitoring plan?
- When should I contact the care team at the CARVYKTI® Certified Treatment Center?

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THE CARVYKTI® TREATMENT PROCESS

STEP 5 Monitoring

CARE PARTNER TIPS

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 CARVYKTI® 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.

Alert the healthcare team quickly if any adverse reactions occur. 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.

Notes

IMPORTANT SAFETY INFORMATION (cont)

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 effects.

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

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Use this space to write down key information, as well as any thoughts, feelings, or reactions you have during this step of the treatment process.

STEP 5 Monitoring

Due to the risk of cytokine release syndrome and neurologic toxicity, both of which can be life-threatening and can lead to death, CARVYKTI® may only be administered at healthcare settings certified in the CARVYKTI® REMS Program.

The goal of the CARVYKTI® REMS is to mitigate the risks of cytokine release syndrome (CRS) and neurologic toxicities.

For more information about the CARVYKTI® REMS Program visit CARVYKTIrems.com.

CRS=cytokine release syndrome.

Notes

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THE CARVYKTI® TREATMENT PROCESS

STEP 5 Monitoring

Notes

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

LONG-TERM CARE AND MONITORING

After the initial **4-week monitoring period** at or near the CARVYKTI® Certified Treatment Center, your team will continue to provide care, and help you with long-term monitoring and regular follow-ups.

Team members from both the Certified Treatment Center and your primary oncology team will continue to stay in touch with you.

There may be certain signs or symptoms of side effects you and your care partner can watch out for. Your primary oncologist will determine if any additional tests are needed. These tests may be blood tests, or questions that you answer or actions you perform.

Let your healthcare team know if you're not feeling well or feel like you're experiencing any signs or symptoms of side effects.

Questions to ask your healthcare team:

- Do I need to make any changes in my diet or in the other medications or herbal or vitamin supplements that I take?
- Are there any signs or symptoms of side effects I should watch out for?
- How do I know my treatment is working?
- How often do I need to follow up with my healthcare team?
- What should my care partner's role be in long-term monitoring?
- Who should my care partner contact if they have questions or concerns?
- Will I have any restrictions on my activities?

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

LONG-TERM CARE AND MONITORING

Use this space to write down your healthcare team's answers to your questions, and any additional questions you or your care partner may have.

Primary oncologist name

Address

Primary nurse contact

Phone number

Notes

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

THE CARVYKTI® TREATMENT PROCESS

LONG-TERM CARE AND MONITORING

Notes

APPOINTMENT CALENDAR

Month:

S	M	T	W	T	F	S

Month:

S	M	T	W	T	F	S

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

APPOINTMENT CALENDAR

Month:

S	M	T	W	T	F	S

Month:

S	M	T	W	T	F	S

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

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 care partners. 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 care partners with support during treatment.

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

- Assistance with transportation, lodging, and out-of-pocket costs related to meals and other expenses related to treatment at the CARVYKTI® Certified Treatment Center

- Support from MyCARVYKTI® Patient Support Specialists, who are available to help guide eligible patients 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

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.

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 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 immunotherapies, especially immune effector cell 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, then returns the rest of the blood to your body. This process may take 3 to 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.

Neurologic toxicities—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 toxicities can result from exposure to substances used in chemotherapy, radiation treatment, drug therapies, organ transplants, or exposure to other substances. Individuals with certain disorders may be especially vulnerable to substances that can cause neurologic toxicities.

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

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.

Before you receive CARVYKTI® tell your healthcare provider about all your medical conditions, including if you have:

- Current or past neurologic problems (such as seizures, stroke, new or worsening memory loss)
- Lung or breathing problems
- Heart problems
- Liver problems
- Kidney problems
- A recent or active infection
- Low blood counts

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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' (loo-kah-fur-ee-sis). 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.

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

IMPORTANT SAFETY INFORMATION (more)

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.

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

In a study comparing CARVYKTI® to standard therapy, there was a higher rate of death in the first 10 months in the CARVYKTI® arm (14%) compared to the standard therapy arm (12%). The increased rate of deaths occurred before receiving CARVYKTI® and after treatment with CARVYKTI®. The reasons for death were progression of multiple myeloma and side effects of the treatment.

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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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

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.

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.

CARVYKTI® may increase your risk of getting cancers including certain types of blood cancers. Your healthcare provider should monitor you for this.

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