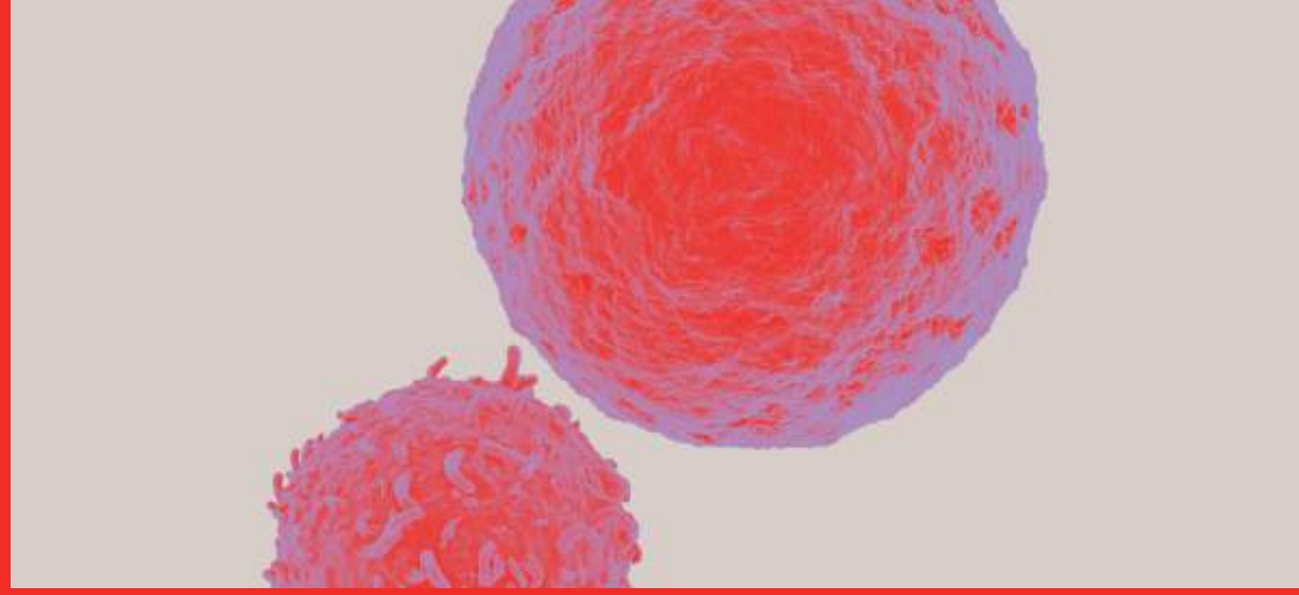

My CAR-T Journey Guide

Important safety and monitoring information for patients

Ciltacabtagene autoleucel
CARVYKTI®▼

For further information please refer to Summary of product characteristics (SPC)

Johnson&Johnson

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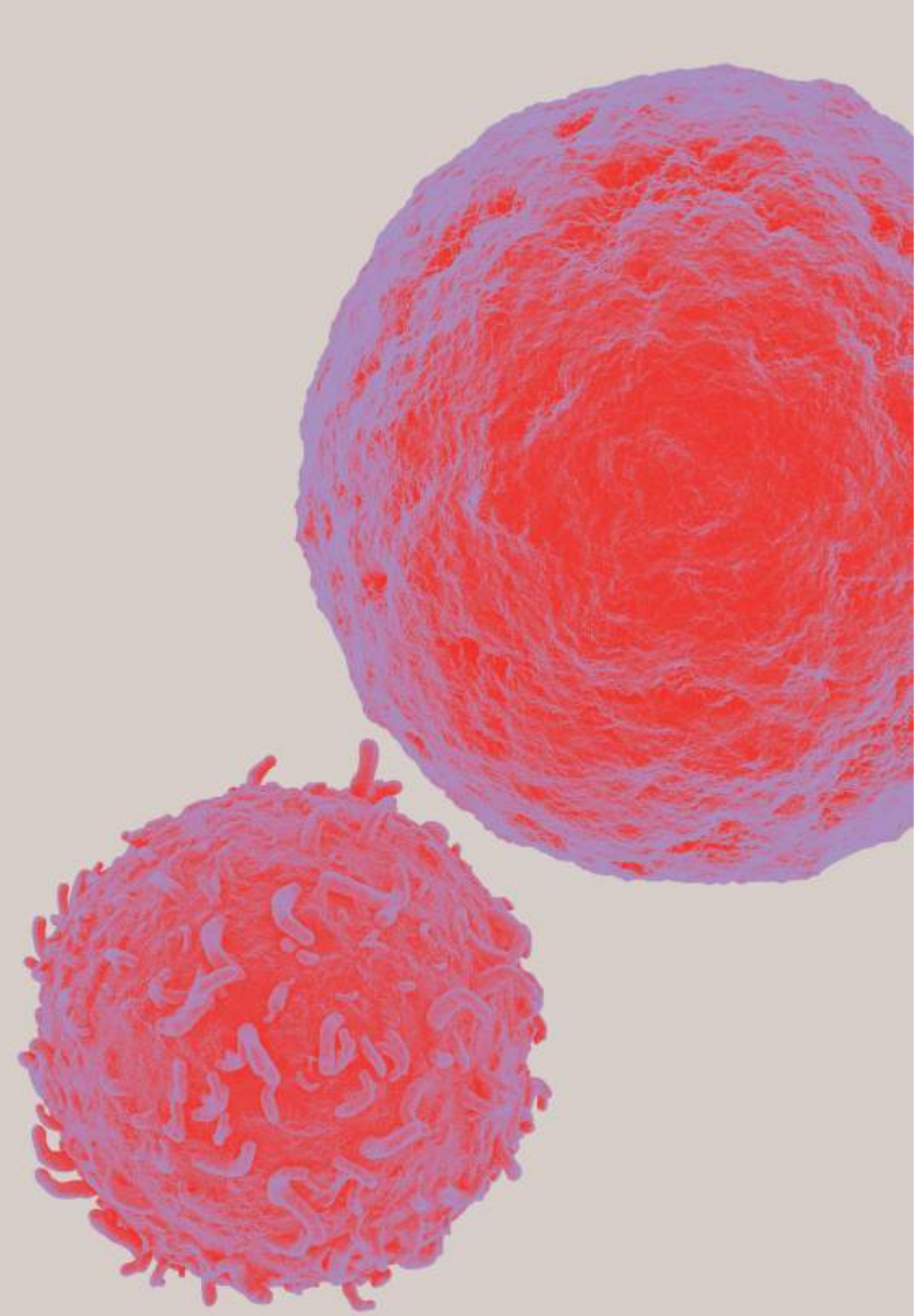

Welcome to the start of your CAR-T journey

To help support you through your CAR-T experience, this guide contains information about the treatment, as well as resources to assist you with questions and logistics around the process. This guide is not meant to replace the Patient Information Leaflet, but to provide you with additional information to help improve your understanding of some of the risks involved with CAR-T cell therapy and help you manage these risks better. This guide and the Patient Information Leaflet will help you understand specific topics that you should become familiar with in order to minimise risk. Each section will help you understand more about what to expect at each step and provide you with details about the visits and assessments that you will experience during CAR-T cell therapy and afterward. Your carer will also play an important role in your CAR-T journey and so should also be familiar with the contents of this guide.

THIS GUIDE BELONGS TO

IF LOST RETURN TO

This guide should not replace the advice and guidance from your healthcare team. If you have additional questions or would like more detailed information please contact your healthcare team.

Placeholder-for local adaption

Some of the sections in this guide are part of the mandatory Risk Management Plan (RMP) for ciltacabtagene autoleucel and are intended to supplement rather than replace the Patient Information Leaflet. These sections are highlighted with a light grey background.

The purpose of a RMP is to educate patients on the various steps and strategies involved in a treatment, and in doing so help to lower the risks associated with treatment.

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Guide Content

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Sections with a light grey background are part of the mandatory Risk Management Plan (RMP) for ciltacabtagene autoleucel

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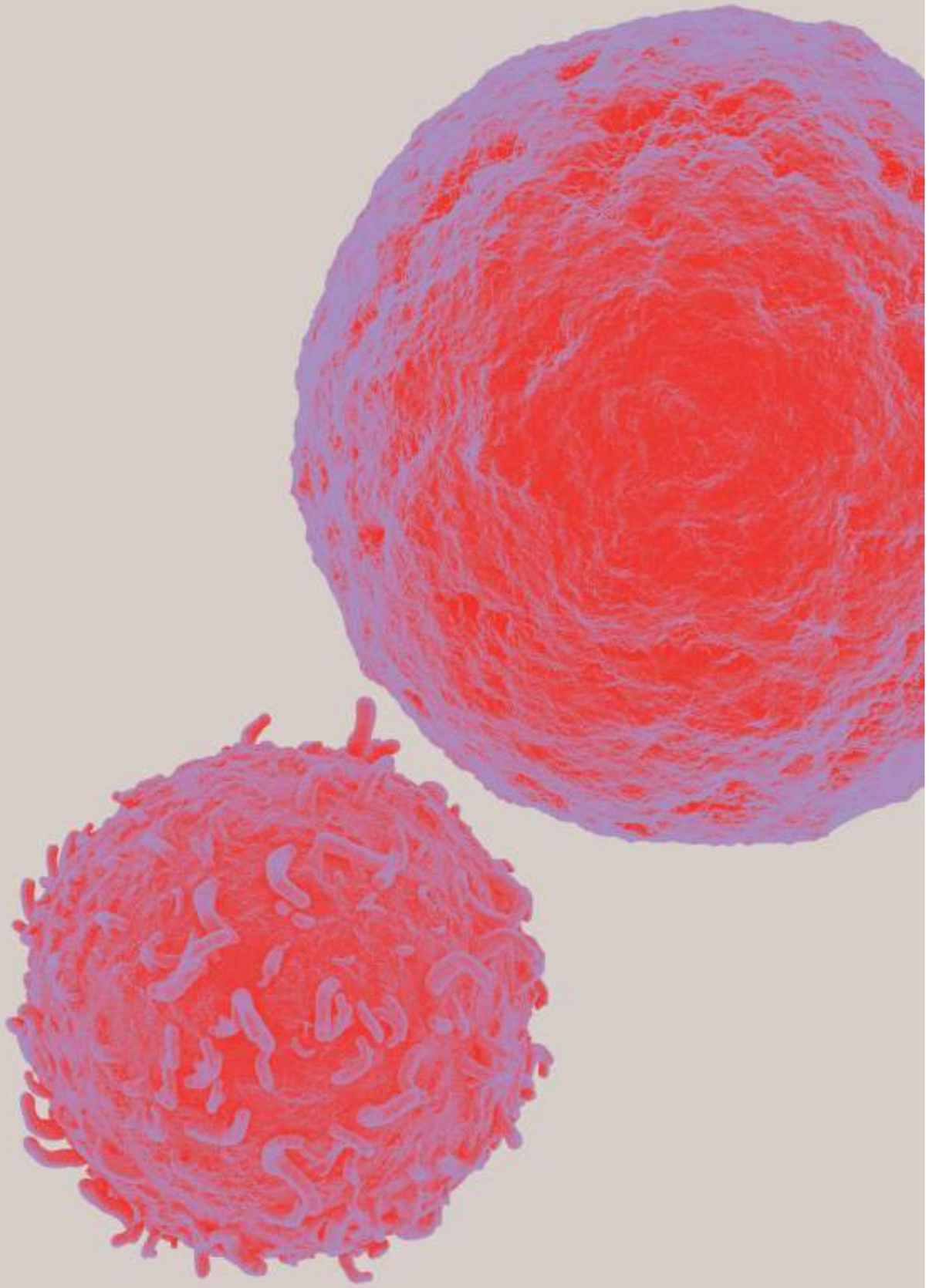

CAR-T overview

What is CAR-T cell therapy?

Chimeric antigen receptor (CAR) T cell therapy is a type of immunotherapy that helps your immune system fight cancer. CAR-T cell therapy can be used to fight multiple myeloma and other diseases. T cells—a type of white blood cell—are part of the immune system and are responsible for attacking any bacteria or foreign cells in the body. During CAR-T cell therapy, some of your own T cells will be collected from you. Your T cells will then be reprogrammed at a manufacturing centre to become CAR-T cells. The CAR-T cells are then reintroduced into your system through an infusion. Once the cells are modified and placed back into your body, they can recognise and attack your multiple myeloma cells.[1–3]

What is ciltacabtagene autoleucel?

Ciltacabtagene autoleucel is a type of CAR-T cell therapy used to treat adult patients with cancer of the bone marrow called multiple myeloma. It is given when at least one other treatment has not worked.[4] Ciltacabtagene autoleucel may also be referred to as ‘cilta-cel’, ‘CARVYKTI®’ or ‘your CAR-T cells’.

Please note that some patients may not be eligible for CAR-T cell therapy.

Eligibility depends on multiple factors, including the patient’s medical history, and will be determined based on patient safety and the likelihood of a positive treatment outcome.[5]

Your eligibility will be assessed by your doctor and specialists from the CAR-T centre. If you are eligible, your doctor will discuss with you whether CAR-T cell therapy is the best therapeutic option.[5]

1. Ali SA, et al. Blood. 2016;128(13):1688–700. 2. Levine BL, et al. Mol Ther Methods Clin Dev. 2016;4:92–101.
3. Janeway CA, et al. In: Immunobiology: The Immune System in Health and Disease, 5th ed; New York: Garland Science; 2001.
4. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.
5. Hayden PJ, et al. Ann Oncol. 2022;33(3):259–275.

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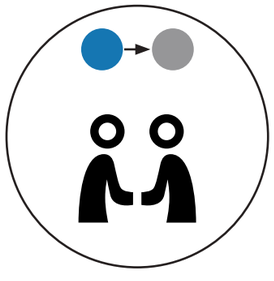
The CAR-T journey

There are five steps involved in your CAR-T cell therapy:[1]

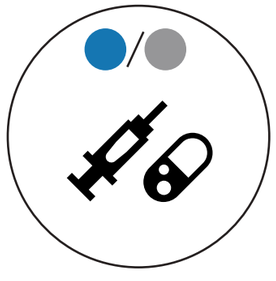


START

Start of my CAR-T journey

STEP 1

Leukapheresis



STEP 2

Bridging therapy

STEP 3

Pre-treatment (lymphodepleting regimen)

STEP 4

CAR-T infusion

STEP 5

Monitoring

CAR-T cell manufacturing

About 4 weeks

Start

After being referred, your CAR-T journey begins when you receive confirmation from the specialist CAR-T centre that you are eligible for CAR-T cell therapy.

STEP 1 – Leukapheresis

Leukapheresis involves the collection of T cells from your blood for use in the CAR-T manufacturing process.

STEP 2 – Bridging therapy

Therapy to control your disease while waiting for your CAR-T cells to be manufactured. Not all patients will need bridging therapy and so some patients may skip Step 2.

STEP 3 – Pre-treatment (lymphodepleting regimen)

Therapy to prepare your body for CAR-T infusion. This will involve a type of chemotherapy.

CAR-T cell manufacturing

Adapts your own T cells to make them more able to recognise myeloma cells. Please see pages 28–30 (CAR-T cell manufacturing guide) for more information.

STEP 4 – CAR-T infusion

Your newly manufactured CAR-T cells are reintroduced to your body intravenously. This is a one-time treatment and you will be monitored closely afterwards.

STEP 5 – Monitoring

Plan to stay near the hospital where you were treated for at least 4 weeks after you are given ciltacabtagene autoleucel.

You will need to return to the hospital every day for at least 14 days after you are given ciltacabtagene autoleucel. This is so your doctor can check if your treatment is working and treat you if you get any side effects.

Referring centre

CAR-T centre

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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This map will help you find where you are in your CAR-T journey and show you what to expect over the course of your treatment. We will go into further detail in the pages that follow.

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CAR-T Process and Timing

Leukapheresis

What should I expect during leukapheresis?

Some of your white blood cells will be collected from you through a process called leukapheresis. This involves drawing your blood into a machine and separating out the T cells, a type of white blood cell, from the rest of your blood. To collect your cells, a small and flexible tube called an intravenous catheter will be placed in your vein to collect blood. After the machine separates the cells from the rest of your blood, the remainder of your blood components are then returned into your vein.[1] If you feel any numbness, a burning feeling or cramps during leukapheresis then you should inform the doctor or nurse immediately and they can help to resolve this. The collected blood cells are then sent for cell manufacturing to make your CAR-T cells. For more info see pages 28–30 (CAR-T cell manufacturing).

It is generally recommended that a carer or travel partner accompany you to your visits. Please discuss if there are any special requirements that apply to your personal circumstances with your healthcare team (e.g. will I need to be in a fasted state?). We have included a list of common questions you may want to ask on pages 24–26.

Timing: Leukapheresis can take 3 to 6 hours and may need to be repeated.[1]

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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Bridging therapy

What is the purpose of bridging therapy?

Once leukapheresis has taken place, your cells are sent to the manufacturing centre where they are modified to make your CAR-T cells. This process takes about 4 weeks.[1] Once ready, the cells are shipped to the CAR-T centre and prepared for your infusion (see pages 28–30 for more detailed information on the CAR-T cell manufacturing process). During this waiting period, you may get other medicines (bridging therapy) to treat the multiple myeloma. This is so it does not get worse.[1] Bridging therapy is intended to stabilise your cancer between leukapheresis and infusion so you may remain eligible to receive CAR-T cells. Therefore, bridging therapy essentially serves as a 'bridge' from one therapy to another. The therapy will be a type of anticancer treatment that your physician will recommend. Talk to your healthcare team about whether bridging therapy is necessary for you. It may be important for your healthcare team and you to plan regular visits during bridging therapy to ensure the therapy is well tolerated and stabilising your disease.

It is generally recommended that a carer or travel partner accompany you to your visits. Please discuss if there are any special requirements that apply to your personal circumstances with your healthcare team. We have included a list of common questions you may want to ask on pages 24–26.

Timing: Bridging therapy will occur between the time of leukapheresis and lymphodepleting chemotherapy. Note that some patients may not need bridging therapy[1].

1. CARVYKTI 3.2 x 10^6 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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Pre-treatment (lymphodepleting regimen)

What should I expect during lymphodepleting chemotherapy?

Between 5 and 7 days before your CAR-T cell infusion, you will undergo lymphodepleting chemotherapy to prepare your body for your CAR-T cells. This treatment reduces the number of white blood cells in your blood, so the genetically modified CAR-T cells can grow in numbers when they are returned to your body. Once your CAR-T cells are ready, you will receive chemotherapy infusions of cyclophosphamide and fludarabine daily for 3 days.[1]

As with most forms of chemotherapy, side effects are expected and can range from mild to severe. For your safety, any side effects should be reported as soon as possible. Common side effects are listed in the table below. Speak with your healthcare team about other potential side effects.

Most common side effects from lymphodepleting chemotherapy: [2,3*]

- Bleeding or bruising easily†
- A lowering of your blood cell counts†
- Infection†
- Vomiting
- Fever
- A burning feeling as you pass urine or blood in your urine
- Hair loss
- Cough
- Feeling tired

*Please see the Patient Information Leaflets for cyclophosphamide[2] and fludarabine[3] for more information.
†These side effects may affect your CAR-T cell therapy and you will be monitored closely.

It is generally recommended that a carer or travel partner accompany you to your visits. Please discuss if there are any special requirements that apply to your personal circumstances with your healthcare team (e.g. logistical arrangements while you undergo the 3 infusions in the hospital if you live further away). We have included a list of common questions you may want to ask on pages 24–26.

Timing: Lymphodepleting chemotherapy will be given to you daily for 3 days starting 5–7 days before receiving your CAR-T cells.[1]

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025
2. Cyclophosphamide 500 mg Package Leaflet. 2019.
3. Fludarabine 50 mg Package Leaflet. 2023.

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Before your CAR-T infusion

You must not be given ciltacabtagene autoleucel if you are allergic to any of the ingredients of this medicine. If you think you may be allergic, ask your doctor for advice. This medicine contains dimethyl sulfoxide (DMSO; a substance used to preserve frozen cells) and may contain traces of kanamycin (an aminoglycoside antibiotic), both of which can sometimes cause allergic reactions. Your doctor will monitor you for any signs of a possible allergic reaction.[1]

Warnings and precautions[1]

Patients treated with ciltacabtagene autoleucel may develop new types of cancers. There have been reports of patients developing cancer, beginning in blood cells, after treatment with ciltacabtagene autoleucel and similar medicines. Talk to your doctor if you experience any new swelling of your glands (lymph nodes) or changes in your skin such as new rashes or lumps.

Tell your doctor before you are given ciltacabtagene autoleucel if you have:

- Current or past problems with your nervous system (such as fits, stroke, new or worsening memory loss).
- Any lung, heart or blood pressure (low or raised) problems.
- Liver or kidney problems.
- Signs or symptoms of graft-versus-host disease. This happens when transplanted cells attack your body, causing symptoms such as rash, nausea, vomiting, diarrhoea and bloody stools.

If any of the above apply to you (or you are not sure), talk to your doctor before you are given ciltacabtagene autoleucel.

Tests and checks[1]

Before you are given ciltacabtagene autoleucel your doctor will:

- Check the levels of blood cells in your blood.
- Check your lungs, heart and blood pressure.
- Look for signs of infection; an infection will be treated before you have ciltacabtagene autoleucel.
- Check if your cancer is getting worse.

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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- Check for hepatitis B, hepatitis C or HIV infection.
- Check if you had a vaccination in the last 6 weeks or plan to have one in the next few months.

Other medicines and ciltacabtagene autoleucel

Self medication (medications that have not been prescribed by your doctor) should be avoided at all times.

Before you are given ciltacabtagene autoleucel tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines, especially medicines that weaken your immune system such as corticosteroids. These medicines may interfere with the effect of ciltacabtagene autoleucel.[1]

Vaccines and ciltacabtagene autoleucel[1]

You must not be given certain vaccines called live vaccines:

- In the 6 weeks before you are given the short course of chemotherapy (called lymphodepleting chemotherapy) to prepare your body for the ciltacabtagene autoleucel cells.
- After ciltacabtagene autoleucel treatment while your immune system is recovering.

Talk to your doctor if you need to have any vaccinations.

Pregnancy and breast-feeding[1]

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine. This is because the effects of ciltacabtagene autoleucel in pregnant or breast-feeding women are not known, and it may harm your unborn baby or your breast-fed child.

If you are pregnant or think you may be pregnant after treatment with ciltacabtagene autoleucel, talk to your doctor immediately.

You have to do a pregnancy test before treatment starts. Ciltacabtagene autoleucel should only be given if the results show you are not pregnant.

If you have had ciltacabtagene autoleucel treatment, you should discuss any plans to have future pregnancies with your doctor.

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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CAR-T infusion

What should I expect during my CAR-T infusion?

A few days after your lymphodepleting chemotherapy ends, your healthcare team will do a final confirmation to make sure you are ready for your CAR-T infusion. Your healthcare team will guide you through how your infusion day will look.

You may be given other medicines 30–60 minutes before infusion. These may include:

- Antihistamine medicines for an allergic reaction such as diphenhydramine.[1]
- Medicines for fever such as paracetamol.[1]

Your doctor or nurse will check carefully that the ciltacabtagene autoleucel treatment you are given is from your own white blood cells.[1]

Ciltacabtagene autoleucel is a one-time treatment. It will not be given to you again.[1]

- Your doctor or nurse will give you ciltacabtagene autoleucel by a drip into your vein. This is called an 'intravenous infusion' and is usually less than 60 minutes.[1]
- Ciltacabtagene autoleucel is the genetically modified version of your white blood cells. Your healthcare professional handling ciltacabtagene autoleucel will take appropriate precautions to prevent the chance of transfer of infectious diseases. They will also follow local guidelines to clean up or dispose of any material that has been in contact with ciltacabtagene autoleucel.[1]

It is generally recommended that a carer or travel partner accompany you to your visits. Please discuss if there are any special requirements that apply to your personal circumstances with your healthcare team. We have included a list of common questions you may want to ask on pages 24–26.

Timing: The infusion will usually be completed in less than 60 minutes.[1]

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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Safety and monitoring after your CAR-T infusion

After receiving your CAR-T infusion, your healthcare team will monitor you to check if your treatment is working and help you if you have any side effects. Plan to stay near the hospital where you were treated for at least 4 weeks after you are given ciltacabtagene autoleucel.[1]

You will need to return to the hospital every day for at least 14 days after you are given ciltacabtagene autoleucel. This is so your doctor can check if your treatment is working and treat you if you get any side effects. If you do develop serious side effects, you may need to stay in the hospital until your side effects are under control and it is safe for you to leave. If you miss any appointments, call your doctor or a qualified treatment centre as soon as possible to make a new appointment.[1]

Ask your healthcare team about a detailed plan for how you will be monitored after the infusion.

For your safety, any side effects experienced following infusion of ciltacabtagene autoleucel, even those that seem minor, should be reported immediately. Because ciltacabtagene autoleucel is a one-time treatment, the emergence of side effects will not affect your treatment. Please speak with your healthcare team about potential side effects.

Recognising an emergency

Ciltacabtagene autoleucel can cause serious side effects that you need to tell your doctor or nurse about straight away.[1] If you or your carer recognise any side effect related to CAR-T cell therapy, it is likely an emergency requiring immediate attention. Patients who have received CAR-T cell therapy have experienced side effects ranging from mild to serious. It is important that you are aware of these possible side effects, as you may experience one or more of them when undergoing CAR-T cell therapy.

It is very important for you to let your healthcare team know immediately about any side effects you might experience throughout your therapy. You can use the monitoring charts on pages 41–48 of this guide to record your temperature and any other symptoms in the 4 weeks after your infusion.

Symptoms requiring urgent medical care may occur at any time after receiving CAR-T cell therapy, however, they typically occur within 1 month after CAR-T infusion.

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Ciltacabtagene autoleucel can cause side effects that may be serious or life-threatening.[1]

Tell your doctor or nurse immediately if you have any of the following:

Cytokine release syndrome (CRS)[1]

- Chills, fever (38° C or higher), fast heart beat, difficulty breathing, low blood pressure which can make you feel dizzy or lightheaded.

These may be signs of a serious immune reaction known as 'cytokine release syndrome' (CRS).

Neurologic toxicities[1]

- Neurologic toxicities occur frequently following treatment with ciltacabtagene autoleucel and can be fatal or life-threatening.
- Effects on your nervous system, symptoms of which can occur days or weeks after you receive the infusion, and may initially be subtle:
  - Feeling confused, less alert, disorientated, anxious or having memory loss*
  - Difficulty speaking or slurred speech*
  - Slower movements, changes in handwriting*
  - Loss of coordination, affecting movement and balance*
  - Difficulty reading, writing and understanding words*
  - Personality changes, which may include being less talkative, disinterest in activities and reduced facial expression

Some of these symptoms may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS) or may be signs and symptoms of parkinsonism. Other neurologic toxicities include movement and neurocognitive toxicity with signs and symptoms of parkinsonism, Guillain-Barré syndrome, peripheral neuropathies and cranial nerve palsies.

Additional side effects

Ciltacabtagene autoleucel may increase the risk of life-threatening infections that may lead to death. Serious immune reactions involving the blood cells may lead to an enlarged liver and spleen, called 'haemophagocytic lymphohistiocytosis'.

Please refer to the ciltacabtagene autoleucel Patient Information Leaflet for more information on other possible side effects you may experience.

Your doctor will regularly check your blood, as the number of blood cells and other blood components may decrease.[1]

*Pay close attention to these and ask your carer to do the same.

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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Other side effects are listed below. Tell your doctor or nurse if you get any of these side effects.

Very common[1]
(may affect more than 1 in 10 people)

- Infected nose, sinuses or throat (a cold)
- Bacterial infection
- Cough, being short of breath
- Pneumonia (lung infection)
- Viral infection
- Headache
- Sleep problems
- Pain, including muscle and joint pain
- Swelling caused by fluid build up in the body
- Feeling very tired
- Nausea (feeling sick), decreased appetite, constipation, vomiting, diarrhoea
- Problems with movement including muscle spasms, muscle tightness
- Nerve damage that may cause tingling, numbness, pain or loss of pain sensation
- Low levels of antibodies called immunoglobulins in the blood – which may lead to infections
- Low level of oxygen in the blood causing shortness of breath, coughing, headache, and confusion
- Increased blood pressure
- Bleeding, which can be severe, called a 'haemorrhage'
- Abnormal blood tests indicating:
  - Low number of white blood cells (including neutrophils and lymphocytes)
  - Low levels of 'platelets' (cells that help blood to clot) and red blood cells
  - Low levels of calcium, sodium, potassium, magnesium, phosphate in the blood
  - Low levels of 'albumin' a type of protein in the blood
  - Blood clotting problems
  - Increased levels of a protein called 'ferritin' in the blood
  - Increased levels of enzymes in the blood called 'gamma-glutamyltransferase' and 'transaminases'

Common[1]
(may affect up to 1 in 10 people)

- Low number of white blood cells (neutrophils), which can occur with infection and fever
- Gastroenteritis (inflamed stomach and gut)
- Stomach pain
- Urinary tract infection
- Fungal infection
- Increased number of a type of white blood cell (lymphocytes)
- Severe infection throughout the body (sepsis)
- Kidney failure
- Abnormal heart beat
- Serious immune reaction involving the blood cells – may lead to an enlarged liver and spleen, called 'haemophagocytic lymphohistiocytosis'
- Serious condition where fluid leaks out of the blood vessels into the body tissues called 'capillary leak syndrome'
- Increased levels of enzymes in the blood called 'alkaline phosphatase'
- Muscle tremor
- Mild muscle weakness caused by nerve damage
- Severe confusion
- Facial numbness, difficulty moving muscles of face and eyes
- High level of 'bilirubin' in the blood
- Blood clot
- Skin rash
- Increased level of a protein called 'C-reactive protein' in the blood that may indicate an infection or inflammation
- A new type of cancer beginning in blood cells and including bone marrow cells

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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Uncommon[1]
(may affect up to 1 in 100 people)

- Tingling, numbness, and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
- A new type of cancer beginning in a type of white blood cells called T cells (secondary malignancy of T-cell origin)

Driving and using tools or machines[1]

Ciltacabtagene autoleucel can severely affect your ability to drive or use tools or machines causing side effects that may make you feel tired, have balance and coordination problems, feel confused, weak or dizzy. Do not drive or use tools or machines until at least 8 weeks after having ciltacabtagene autoleucel and if these symptoms return.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse.[1] Do not try to treat your symptoms with other medicines on your own. This includes any other side effects not listed in this guide. You can also report side effects directly via the national reporting system listed in.

Adverse events reporting guidance:

- The National Pharmacovigilance Centre (NPC), SFDA:
- Email: npc.drug@sfda.gov.sa
- Telephone: 19999
- Online: http://ade.sfda.gov.sa

For full prescribing information, please refer to the datasheet or contact **Johnson & Johnson Trading Limited (Riyadh)**

- Address: Prince Muhammed Bin Abdulaziz Rd, Tower B, Level 30, Olaya towers.
- Office Tel: 00966-11-4339133
- Postal address: P O Box 65305 Riyadh 11556, Saudi Arabia
- **To report Adverse Events/Product Complaint or any Medical Information Inquiries, please contact us at:**

  Email: GCC-PV2@its.jnj.com

  Hotline: 00966540015811

By reporting side effects you can help provide more information on the safety of this medicine.[1]

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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Long-term safety monitoring

CAR-T cell therapy is a new type of therapy for multiple myeloma. Therefore, there is a requirement to collect long-term follow-up data on patients treated with CAR-T cell therapy in order to better understand the long-term effects.

Additional considerations

- Please note: a bone marrow biopsy may be required in order to perform an assessment of minimal residual disease (MRD). This test looks for cancer cells that may still be present following CAR-T cell therapy and can help determine the effectiveness of the treatment.
- Having ciltacabtagene autoleucel in your blood may cause some commercial HIV tests to incorrectly give you a HIV positive result even though you may be HIV negative.[1]
- Do not donate blood, organs, tissues or cells for transplants after you have had ciltacabtagene autoleucel.[1]

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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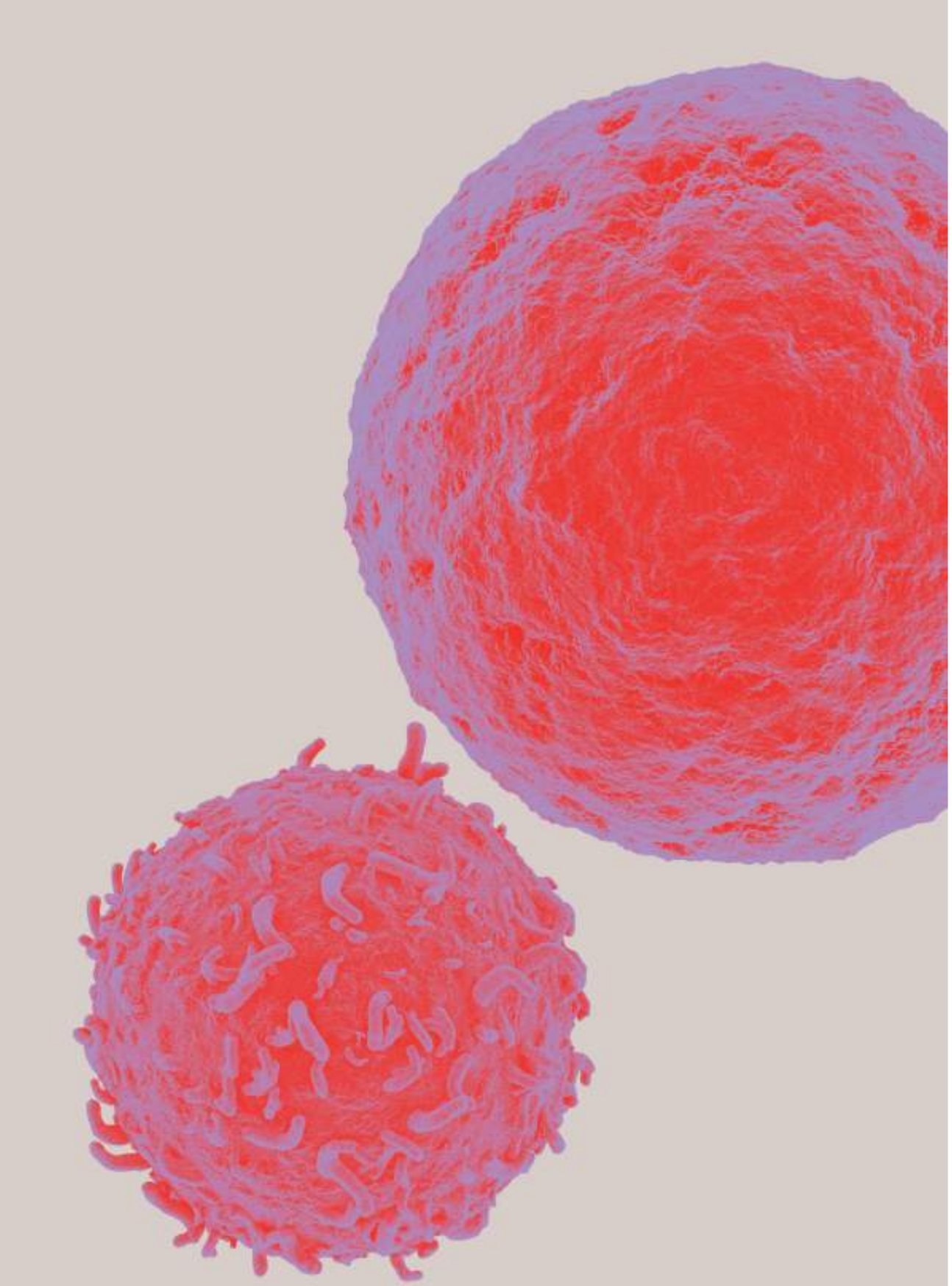

Planned CAR-T visits guide

How to best plan for your CAR-T procedures and treatments

During CAR-T cell therapy, you will visit your healthcare team for the necessary procedures and treatments detailed in the previous pages. It is recommended that someone accompanies you to each visit and that you or your carer prepare questions for your healthcare team.

Common questions to consider asking your healthcare team before each procedure or treatment:

IN PREPARATION

- **How should I prepare?**
  (e.g. Will this be a long day because I will have leukapheresis or receive multiple medications/infusions during bridging therapy or lymphodepleting chemotherapy?).

- **Is there any medical history I should disclose in preparation?**
  (e.g. Are there any cardiac disorders such as heart failure or medical devices such as pacemakers? Is there any known decrease in kidney function? Is there any underlying lung disease such as chronic obstructive pulmonary disease [COPD] or asthma?). Please refer to pages 15–16 (Before Your CAR-T Infusion) for more information.

- **Can I take any other medications?**
  (e.g. Can I continue to take other prescribed medications during CAR-T cell therapy? What about herbal or vitamin supplements?). Please refer to pages 15–16 (Before Your CAR-T Infusion) for more information.

- **Are there any diet restrictions before or during?**
  (e.g. Do I have to come in a fasted state or remain fasted for a prolonged period of time because a central line or another procedure is scheduled later in the day?).

- **Should I plan to stay longer than the actual day of the procedure or treatment?**
  (e.g. Will any of the procedures or treatments require hospitalisation? If I am hospitalised, can carers visit or stay with me?).

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DAY OF

- **What will the set-up be like?**
  (e.g. Will I have to lie down, or can I sit in a chair to have my leukapheresis, bridging therapy, lymphodepleting chemotherapy or CAR-T infusion?).

- **Is there anything specific I should pack to bring with me?**
  (e.g. If I am preparing for a long day, is it possible to bring books/iPad and other forms of entertainment? Can I bring food/drinks? Can my carer or travel partner stay with me during the treatment or procedure?).

- **Where will it take place?**
  (e.g. Will it be a routine visit at my normal CAR-T site location at the hospital or will it be at a separate department/building for leukapheresis? Will some of the visits take place at my local general practitioner or oncologist/haematologist's offices?).

- **Who will administer the procedure or treatment?**
  (e.g. If a central line needs to be placed, will it be an anaesthesiologist/radiologist or my normal oncologist or haematologist who will do this?).

AFTER

- **What are the potential side effects?**
  (e.g. What are potential side effects from leukapheresis? What are common side effects of bridging and lymphodepleting chemotherapy? What are common side effects of CAR-T cell therapy, when are they expected to occur, and how long are they expected to last?). Please refer to pages 18–22 (Safety and Monitoring after CAR-T Infusion) for more information.

More space for your own notes is provided towards the end of this guide, on pages 36–38.

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ACTIVITIES AND TRAVEL

- **What activities should I avoid before or after?**
  (e.g. Should I refrain from driving myself to and from the appointment because I will receive a medication that may cause drowsiness?). Please refer to pages 18–21 (Safety and Monitoring after CAR-T Infusion) for more information.

- **Can I resume normal daily activities after?**
  (e.g. Can I continue to pursue daily exercise or outdoor activities? Is it OK to drink alcohol or smoke cigarettes?).

- **Will there be any limitations after?**
  (e.g. Should I take any precautions in terms of social distancing in order to avoid contracting an infectious disease during a time when my blood counts are low?).

- **Are there any movement or travel restrictions after?**
  (e.g. When can I plan to attend family events or schedule holidays further away from my treatment location?).

RESOURCES

- **What can I do to support my emotional well-being during this period?**
  (e.g. How have other patients managed the time between leukapheresis and CAR-T cell therapy? Will my healthcare team have information about where my cells are in the manufacturing process?).

- **What resources are available for me during this period?**
  (e.g. Can you recommend resources on your site or from patient advocacy groups that could help me and my family during this journey? How can I best plan my travel during this therapy?).

SAFETY AND EMERGENCY CONTACT INFORMATION

- **What happens if I catch a cold or other illness at any point?**
  (e.g. When should I notify my healthcare team of an illness and what should I do?).

- **Who can I contact if I have any further questions?**
  (e.g. Can you provide me with a 24/7 available point of contact that I can reach via phone in case of an emergency?).

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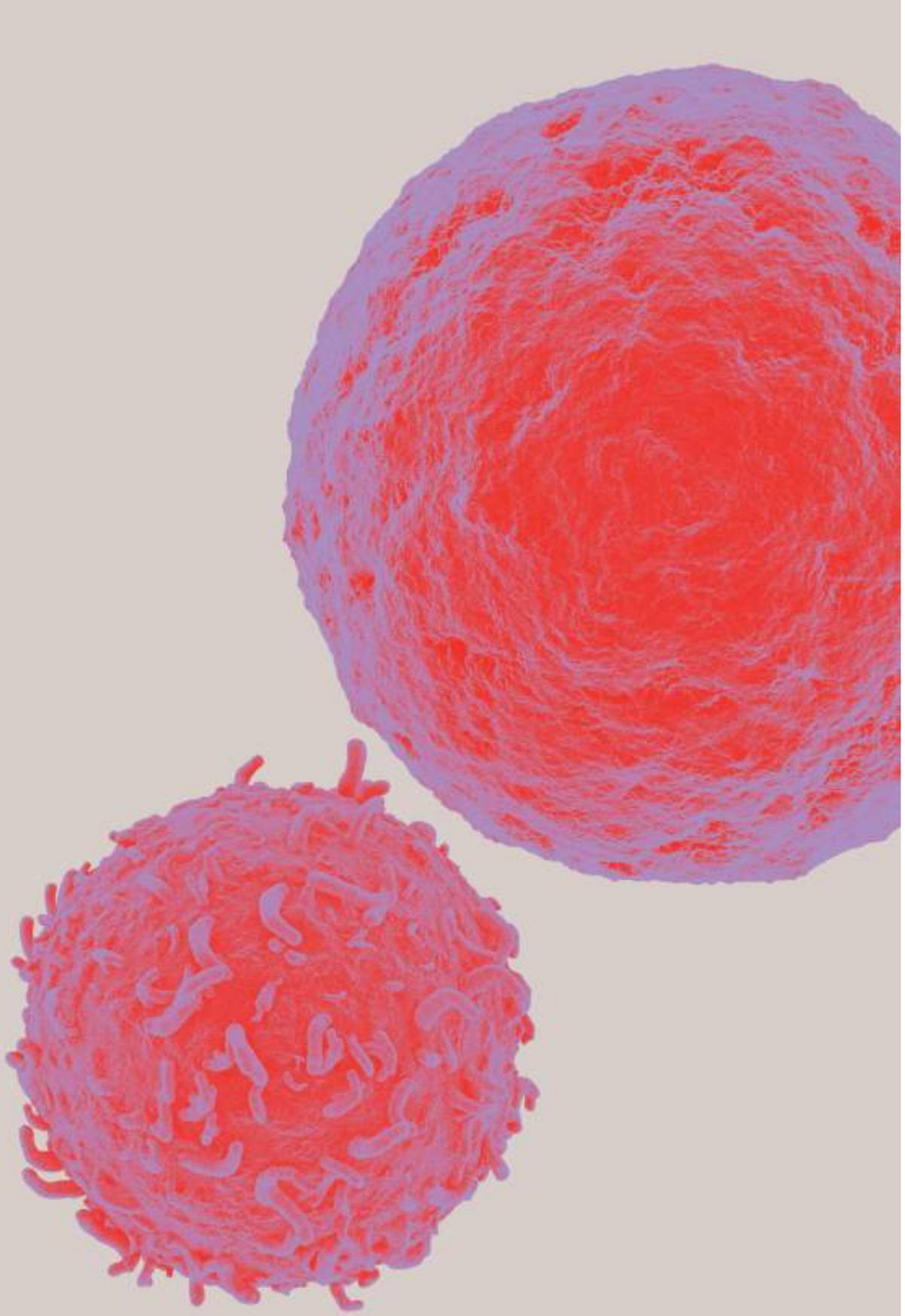

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CAR-T cell manufacturing

What happens during CAR-T cell manufacturing?

After your cells are collected during leukapheresis, they are frozen in liquid nitrogen and shipped to a manufacturing centre. At the cell manufacturing centre, your T cells will be reprogrammed into CAR-T cells using non-infectious viruses called lentiviral vectors to change the way they express proteins on their surface.[1] The CAR-T cells will then express new proteins which allow them to recognise and attack your cancer cells. In the case of ciltacabtagene autoleucel, the CAR-T cells are programmed to target cells expressing B-cell maturation antigen (BCMA),[1] a protein found in large amounts on multiple myeloma cells.[2] Once the CAR-T cells are ready and have been checked for safety and quality, they will be reintroduced to your body during infusion.

A member of your healthcare team will notify you when your CAR-T cells have completed the manufacturing process.

Timing: While ciltacabtagene autoleucel is made (this takes about 4 weeks) you may get other medicines to treat the multiple myeloma. This is so it does not get worse.[1]

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.
2. Tai YT and Anderson KC. Expert Opin Biol Ther. 2019;19(11):1143–1156.

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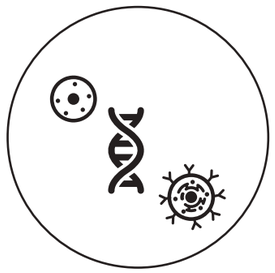
CAR-T cell manufacturing

The diagram below shows the journey your T cells take to become the CAR-T cells you will receive during infusion:

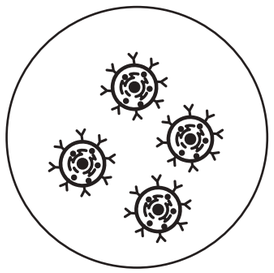
STEP 1

Blood cells are frozen and shipped to manufacturing site



STEP 2

Cells are thawed and engineered to make CAR-T cells



STEP 3

Cells are grown and undergo several quality control checks

STEP 4

CAR-T cells are frozen and shipped to infusion centre

STEP 5

CAR-T cells arrive at infusion centre

Timing: It will take about 4 weeks to manufacture your CAR-T cells.[1]

1. CARVYKTI 3.2 x 10^6–1.0 x 10^8 cells dispersion for infusion. Saudi Summary of Product Characteristics, January 2025.

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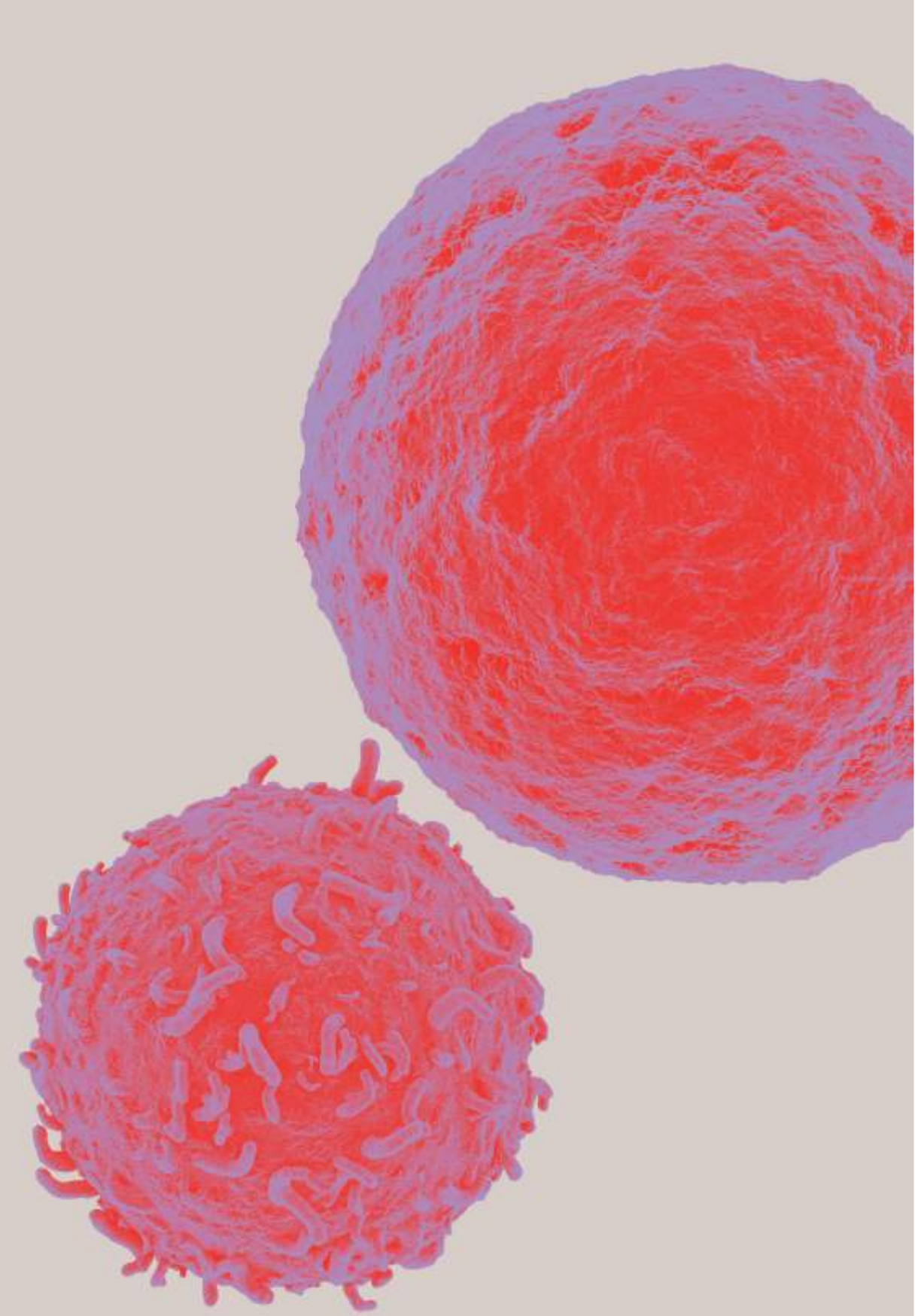

Patient support and resources

Travel assistance

We know setting up travel for your CAR-T journey can be a burden that adds to the stress of getting therapy. There may be resources available to help make this process easier. Talk to your healthcare team to learn more about your options.

Notes from your healthcare team

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Healthcare team information

Healthcare team contact information

It is important to know who is on your healthcare team and how to get in contact with them. Please use the space below to write down their contact information and function/title (e.g. CAR-T Nurse, CAR-T Coordinator, CAR-T Physician)

Contact details of the CAR-T site

24/7 EMERGENCY PHONE NUMBER:

PRIMARY CAR-T HEALTHCARE PROFESSIONAL:

ADDRESS:

NAME:

PHONE NUMBER:

FUNCTION/TITLE:

BEST TIME TO REACH:

EMAIL:

NAME:

PHONE NUMBER:

FUNCTION/TITLE:

BEST TIME TO REACH:

EMAIL:

NAME:

PHONE NUMBER:

FUNCTION/TITLE:

BEST TIME TO REACH:

EMAIL:

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Notes

Notes/questions:

These notes are for your personal use. You may wish to write down questions to raise with your healthcare team. This could include questions about any side effects that you have experienced and these should always be discussed with your doctor or healthcare team.

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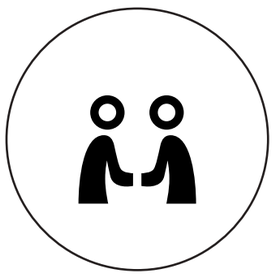
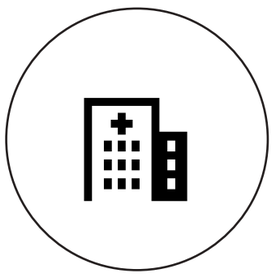
My CAR-T timeline



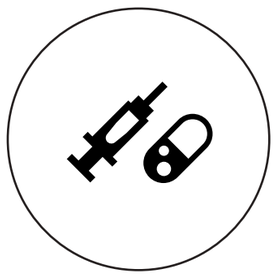
START

Start of my CAR-T journey



STEP 1

Leukapheresis

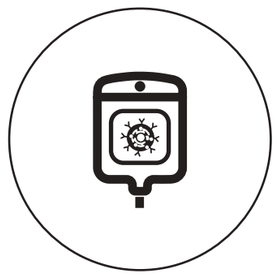


STEP 2

Bridging therapy

STEP 3

Pre-treatment (lymphodepleting regimen)



STEP 4

CAR-T infusion

STEP 5

Monitoring after infusion

CAR-T cell manufacturing

Date of leukapheresis:

Start date of bridging therapy:

End date of bridging therapy:

First infusion of pre-treatment (lymphodepleting regimen):

Second infusion of pre-treatment (lymphodepleting regimen):

Third infusion of pre-treatment (lymphodepleting regimen):

Date of CAR-T infusion:

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Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 1 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							

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Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 2 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							

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Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 3 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							

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Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 4 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							

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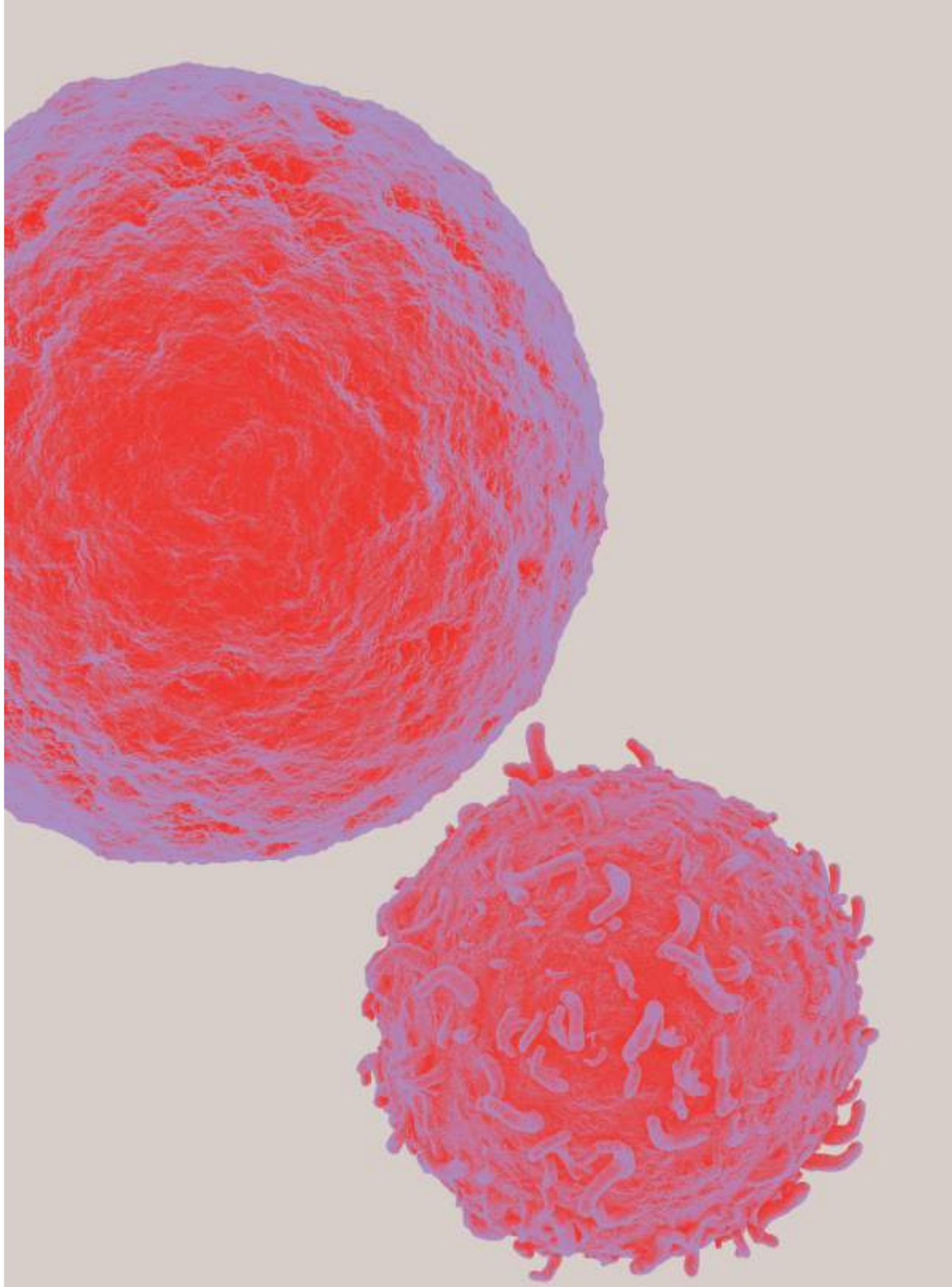
Glossary

BCMA	B-cell maturation antigen
CAR	Chimeric antigen receptor
COPD	Chronic obstructive pulmonary disease
CRS	Cytokine release syndrome
DMSO	Dimethyl sulfoxide
HIV	Human immunodeficiency virus
ICANS	Immune effector cell-associated neurotoxicity syndrome
MRD	Minimal residual disease
RMP	Risk management plan



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Adverse events reporting guidance:

- The National Pharmacovigilance Centre (NPC), SFDA:
- Email: npc.drug@sfda.gov.sa
- Telephone: 19999
- Online: http://ade.sfda.gov.sa

For full prescribing information, please refer to the datasheet or contact **Johnson & Johnson Trading Limited (Riyadh)**

- Address: Prince Muhammed Bin Abdulaziz Rd, Tower B, Level 30, Olaya towers.
- Office Tel: 00966-11-4339133
- Postal address: P O Box 65305 Riyadh 11556, Saudi Arabia
- **To report Adverse Events/Product Complaint or any Medical Information Inquiries, please contact us at:**

  Email: GCC-PV2@its.jnj.com

  Hotline: 00966540015811

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