UNDERSTANDING CAR-T THERAPY

CAR-T therapy=**C**himeric **A**ntigen **R**eceptor **T** cell therapy

IMPORTANT INFORMATION ABOUT THIS TREATMENT OPTION

janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

LEGEND BIOTECH

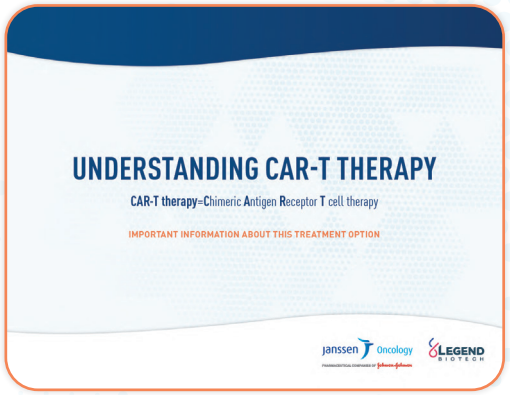
Introduction

KEY TAKEAWAY

- Introduce CAR-T therapy

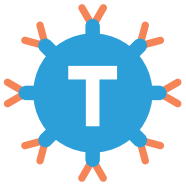
TALKING POINTS

- CAR-T therapy stands for **C**himeric **A**ntigen **R**eceptor **T** cell therapy
- We're going to review some information you need to know about this treatment option



Patient View

What is CAR-T therapy?



CAR-T THERAPY USES YOUR OWN IMMUNE SYSTEM TO FIGHT CANCER

- CAR-T therapy is different from other cancer treatments
  - It is made from specific types of your own white blood cells called T cells
  - CAR-T therapy genetically modifies your T cells to recognize and attack a target found on the outside of cancer cells and some other cells

WHAT IS CAR-T THERAPY PRESCRIBED FOR?

- CAR-T therapy is a type of treatment for certain types of blood cancers, including some leukemias and lymphomas, and for multiple myeloma
- Blood cancer refers to cancer that starts and circulates in your blood and/or lymphatic system, or bone marrow

CAR-T THERAPY IS A ONE-TIME INFUSION

While CAR-T is a one-time infusion, it is part of a 5-step process:

1. Collection of T cells
2. Genetic modification of T cells to personalize CAR-T cells
3. Chemotherapy preparation for the CAR-T infusion
   - Bridging therapy may be prescribed while waiting for your CAR-T cells
4. A one-time infusion of the CAR-T cells
5. Side effect monitoring after infusion

What is CAR-T therapy?

KEY TAKEAWAYS

- CAR-T therapy is a type of treatment for certain types of cancers. It has been FDA approved to treat relapsed/refractory multiple myeloma, as well as some kinds of lymphoma and leukemia[1-7]
- CAR-T therapy is personalized for each individual patient using T cells from that patient's own immune system[1]
- CAR-T therapy is a one-time infusion, as part of a 5-step process[8]

TALKING POINTS

- CAR-T therapy is different from other commonly used cancer treatments, such as chemotherapy and stem cell transplant[1-7,9-14]
  - What makes it different is that CAR-T therapy is a customized treatment using a patient's T cells
  - CAR-T therapy genetically modifies your own T cells so that they can recognize and attack a target found on the outside of cancer cells and some other cells
  - CAR-T therapy is also different because the treatment is delivered in a one-time infusion, as part of a 5-step process
- There are certain criteria that need to be met in order to be eligible for CAR-T therapy. Please talk to your physician if you have questions about these criteria[11-13,15]:
  - Disease not likely to rapidly progress
  - Use is consistent with product labeling (and, if being used in a clinical trial setting, meets trial criteria)
  - Patient in general good health with good performance status (Eastern Cooperative Oncology Group score 0-1)
  - Patient has a support system for patient journey

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Personalized CAR-T therapy vs other treatments
- Studies on CAR-T therapy

Patient View

AS YOU MAY KNOW...

CAR-T therapies are currently in development for a variety of diseases and illnesses, including:

Solid-tumor cancers
- Glioblastoma
- Colorectal cancer
- Pancreatic cancer
- Gastric cancer
- Hepatocellular carcinoma
- Prostate cancer
- Ovarian cancer
- Breast cancer
- Lung cancer

Hematologic cancers
- Multiple myeloma*
- Non-Hodgkin lymphomas*
- T cell malignancies*
- Recurrent chronic lymphocytic leukemia

*Diseases where CAR-T therapies have been FDA approved since 2017.

Viruses
- Human immunodeficiency virus
- Hepatitis B virus
- Hepatitis C virus
- Human cytomegalovirus
- Epstein-Barr virus

Other infectious diseases
- Aspergillus fumigatus (fungal infection)

References: 1. National Cancer Institute. CAR T-cell therapy Published 2019. Accessed January 30, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy **2.** Abecma® (idecabtagene vicleucel). Prescribing Information. Bristol-Myers Squibb Company; 2021. **3.** Breyanzi® (lisocabtagene maraleucel). Prescribing Information. Summit, NJ: Bristol-Myers Squibb Company; 2022. **4.** CARVYKTI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **5.** Kymriah® (tisagenlecleucel). Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2022. **6.** Yescarta® (axicabtagene ciloleucel). Prescribing Information. Kite Pharma, Inc; 2022. **7.** Tecartus® (brexucabtagene autoleucel). Prescribing Information. Kite Pharma, Inc; 2021. **8.** Majzner RG, Mackall CL. Clinical lessons learned from the first leg of the CAR T cell journey. *Nat Med.* 2019;25(9):1341-1355. **9.** Wang X, Rivière I. Clinical manufacturing of CAR T cells: foundation of a promising therapy. *Mol Ther Oncolytics.* 2016;3:16015. **10.** ClinicalTrials.gov. Leukapheresis for CAR or Adoptive Cell Therapy Manufacturing. ClinicalTrials.gov Identifier: NCT03226704. Updated January 10, 2023. Accessed January 31, 2023. https://clinicaltrials.gov/ct2/show/NCT03226704 **11.** Garcia A, Keinonen S, Sanchez AM, Ferrari G, Denny TN, Moody MA. Leukopak PBMC sample processing for preparing quality control material to support proficiency testing programs. *J Immunol Methods.* 2014;409:99-106. **12.** Perica K, Curran KJ, Brentjens RJ, Giralt SA. Building a CAR garage: preparing for the delivery of commercial CAR T products at Memorial Sloan Kettering Cancer Center. *Biol Blood Marrow Transplant.* 2018;24(6):1135-1141. **13.** Dave H, Jerkins L, Hanley PJ, Bollard CM, Jacobsohn D. Driving the CAR to the bone marrow transplant program. *Curr Hematol Malig Rep.* 2019;14(6):561-569. **14.** Beaupierre A, Lundberg R, Marrero L, Jain M, Wang T, Alencar MC. Management across settings: an ambulatory and community perspective for patients undergoing CAR T-cell therapy in multiple care settings. *Clin J Oncol Nurs.* 2019;23(2):27-34. **15.** Chow VA, Shadman M, Gopal AK. Translating anti-CD19 CAR T-cell therapy into clinical practice for relapsed/refractory diffuse large B-cell lymphoma. *Blood.* 2018;132(8):777-781.

When is CAR-T therapy used?

WHEN IS CAR-T THERAPY USED?

- CAR-T therapies are used at different stages for different diseases once you and your doctor have determined it is right for you
- Research related to CAR-T therapies continues to evolve, so make sure to talk to your doctor about any new developments

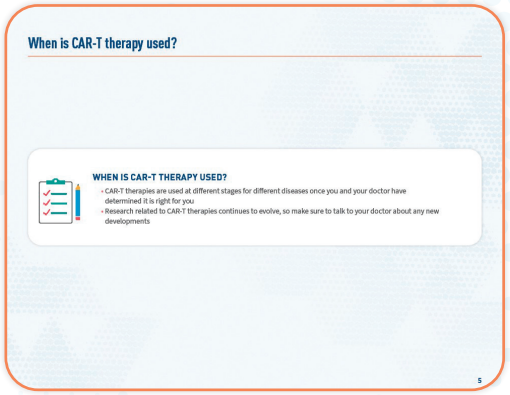
When is CAR-T therapy used?[1-8]

KEY TAKEAWAY

- CAR-T therapy is used at different stages for different diseases as the research continues to evolve

TALKING POINTS

- CAR-T therapies are used at different stages for different diseases once you and your doctor have determined it is right for you
- Research related to CAR-T therapies continues to evolve, so make sure to talk to your doctor about any new developments



Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

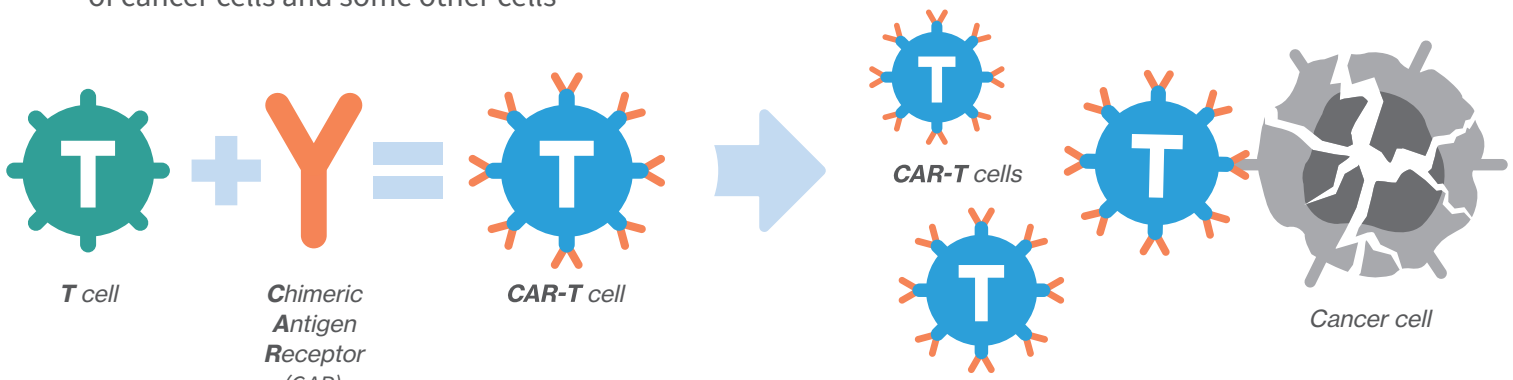
- Patient eligibility in the relapsed setting
- Treatment decision-making

References: 1. Abecma® (idecabtagene vicleucel). Prescribing Information. Bristol-Myers Squibb Company; 2021. **2.** Breyanzi® (lisocabtagene maraleucel). Prescribing Information. Summit, NJ: Bristol-Myers Squibb Company; 2022. **3.** CARVYKTI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **4.** Kymriah® (tisagenlecleucel). Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2022. **5.** Yescarta® (axicabtagene ciloleucel). Prescribing Information. Kite Pharma, Inc; 2022. **6.** Tecartus® (brexucabtagene autoleucel). Prescribing Information. Kite Pharma, Inc; 2021. **7.** Majzner RG, Mackall CL. Clinical lessons learned from the first leg of the CAR T cell journey. *Nat Med.* 2019;25(9):1341-1355. **8.** Martin T, Usmani SZ, Schecter JM, et al. Matching-adjusted indirect comparison of efficacy outcomes for ciltacabtagene autoleucel in CARTITUDE-1 versus idecabtagene vicleucel in KarMMa for the treatment of patients with relapsed or refractory multiple myeloma. *Curr Med Res Opin.* 2021;37(10):1779-1788.

How does CAR-T therapy work?

CAR-T THERAPY USES YOUR OWN CELLS TO FIGHT CANCER

- In CAR-T therapy, your own T cells are collected and genetically modified
- Chimeric antigen receptors (CARs) are added to the T cell to become CAR-T cells
- CAR-T cells are returned to your body in a one-time infusion
- CAR-T cells can find specific targets on the surface of cancer cells and attack a target found on the outside of cancer cells and some other cells



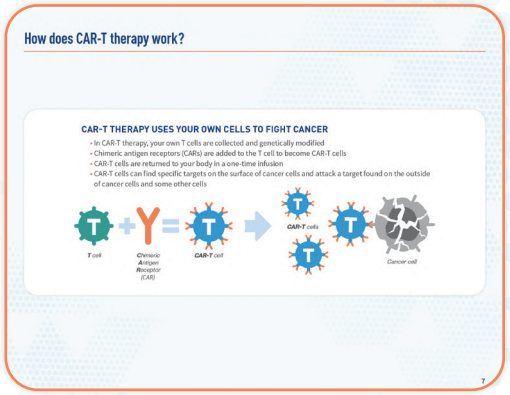
How does CAR-T therapy work?

KEY TAKEAWAYS

- CAR-T therapy uses a person's own T cells to fight cancer[1,2]
- T cells are genetically modified into CAR-T cells[1,2]
- CAR-T therapy is given as a one-time infusion[1]

TALKING POINTS

- T cells are members of the immune system that attack infection and disease[3]
- Sometimes, cancer cells are not detected by T cells and evade attack[4]
- CAR-T therapy takes your own T cells and genetically modifies them so that they can recognize and destroy cancer cells[1,2]
- A new part is added to the T cells, called CAR
- These modified CAR-T cells are returned to your body via a one-time infusion[1]



Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- T cell collection process
- CAR-T cell infusion

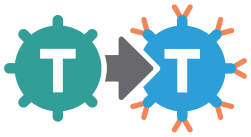
References: 1. Majzner RG, Mackall CL. Clinical lessons learned from the first leg of the CAR T cell journey. *Nat Med.* 2019;25(9):1341-1355. **2.** National Cancer Institute. CAR T-cell therapy. Accessed January 30, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy **3.** National Cancer Institute. T cell. Accessed January 30, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/t-cell **4.** Han Y, Liu D, Li L. PD-1/PD-L1 pathway: current researches in cancer. *Am J Cancer Res.* 2020;10(3):727-742.

The CAR-T treatment process

THE CAR-T TREATMENT PROCESS FROM CELL COLLECTION THROUGH MONITORING

- The decision to prescribe CAR-T therapy is usually a collaborative one between your primary oncologist and a treating physician at a Certified Treatment Center. Together, they'll assess whether CAR-T therapy is right for you

STEP 1
CELL COLLECTION



STEP 2
MODIFYING YOUR T CELLS

STEP 3
PRE-INFUSION TREATMENT

STEP 4
ONE-TIME CAR-T INFUSION

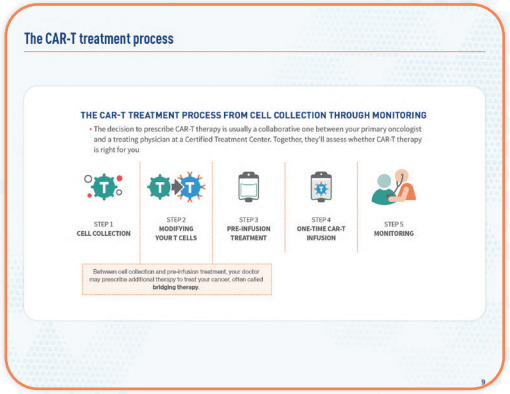
STEP 5
MONITORING

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

The CAR-T treatment process

KEY TAKEAWAYS

- CAR-T is a highly personalized treatment that is manufactured individually for each patient[1,2]
- CAR-T therapy can be administered only by a specially trained healthcare team at a Certified Treatment Center[3]



Patient View

TALKING POINTS

- The decision to prescribe CAR-T therapy to a patient is usually a collaborative decision between your primary oncologist and a treating physician at a Certified Treatment Center. Together, they'll assess whether CAR-T therapy is right for you[4]
- Once you've been prescribed CAR-T, the treatment process proceeds across 5 steps from cell collection through monitoring after the infusion of your CAR-T cells[2,5,6]
- You'll need to stay at or near the location where you received your CAR-T infusion for at least 4 weeks (timing may vary depending on patient and product) after your infusion so your healthcare team at the Certified Treatment Center can monitor you for side effects[4]
- The next few pages will cover each step of the CAR-T treatment process in greater detail

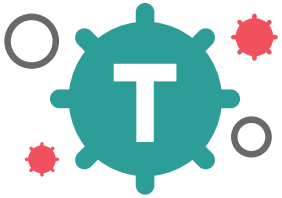
PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Length of total treatment time
- Frequency of travel for treatment
- Location for treatment

References: 1. Majzner RG, Mackall CL. Clinical lessons learned from the first leg of the CAR T cell journey. *Nat Med.* 2019;25(9):1341-1355. **2.** National Cancer Institute. CAR T-cell therapy. Accessed January 30, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy **3.** Beaupierre A, Lundberg R, Marrero L, Jain M, Wang T, Alencar MC. Management across settings: an ambulatory and community perspective for patients undergoing CAR T-cell therapy in multiple care settings. *Clin J Oncol Nurs.* 2019;23(2):27-34. **4.** Beaupierre A, Kahle N, Lundberg R, Patterson A. Educating multidisciplinary care teams, patients, and caregivers on CAR T-cell therapy. *J Adv Pract Oncol.* 2019;10(suppl 3):29-40. **5.** Perica K, Curran KJ, Brentjens RJ, Giralt SA. Building a CAR garage: preparing for the delivery of commercial CAR T products at Memorial Sloan Kettering Cancer Center. *Biol Blood Marrow Transplant.* 2018;24(6):1135-1141. **6.** Wang X, Rivière I. Clinical manufacturing of CAR T cells: foundation of a promising therapy. *Mol Ther Oncolytics.* 2016;3:16015.

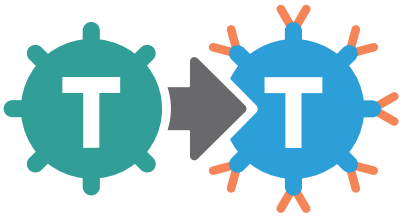
The CAR-T treatment process (more)

STEP 1: CELL COLLECTION



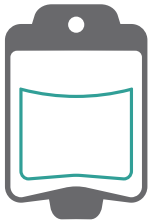
- Your T cells are collected using a process called leukapheresis
- Leukapheresis uses a machine to separate white blood cells (including T cells) and returns the rest of the blood into your body

STEP 2: MODIFYING YOUR T CELLS



- Your white blood cells are sent to a manufacturing site, where the T cells are isolated and modified to include specialized receptors
- These CAR-T cells can recognize and attach to a target on the surface of cancer cells

STEP 3: PRE-INFUSION TREATMENT



- About a week before receiving your CAR-T cells, you'll receive infusions of low-dose chemotherapy
- These infusions are given to clear out some of your white blood cells
- This is called lymphodepletion and helps create space in your body for your new CAR-T cells to grow

BETWEEN CELL COLLECTION AND PRE-INFUSION TREATMENT, YOUR DOCTOR MAY PRESCRIBE ADDITIONAL THERAPY TO TREAT YOUR CANCER, OFTEN CALLED BRIDGING THERAPY.

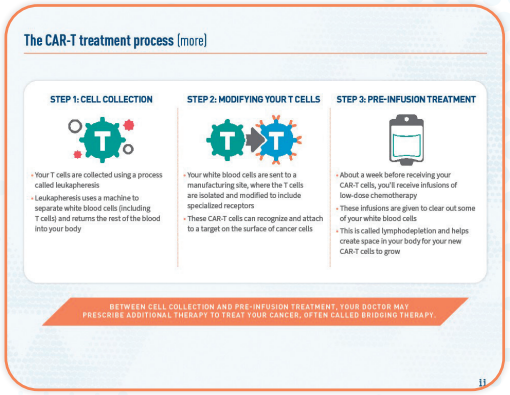
The CAR-T treatment process (more)

KEY TAKEAWAYS

- Steps 1 and 2 begin the highly individualized process by collecting and modifying the patient's T cells so they can recognize cancer cells[1-3]
- Step 3 involves pre-infusion treatments that help prepare the patient's body for their CAR-T infusion[1,4]

TALKING POINTS

- **STEP 1—CELL COLLECTION[3]**
  - Leukapheresis is used to collect some of the white blood cells (including T cells)
- **STEP 2—MODIFYING YOUR T CELLS[1,2,5,6]**
  - At a manufacturing site, the T cells are isolated and modified to include specialized receptors that can recognize and destroy cancer cells
  - During this process, the cells are growing and expanding
- **STEP 3—PRE-INFUSION TREATMENT[1,2,4]**
  - About a week before receiving your CAR-T cells, you'll receive infusions of low-dose chemotherapy
  - These infusions of low-dose chemotherapy help clear out some of your white blood cells so that your new CAR-T cells have room to grow inside of you
  - This is called lymphodepletion



Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Information the patient should request from their primary oncologist
- Potential time delays during the CAR-T treatment process
- Potential repetition of any part of the process

References: 1. Perica K, Curran KJ, Brentjens RJ, Giralt SA. Building a CAR garage: preparing for the delivery of commercial CAR T products at Memorial Sloan Kettering Cancer Center. *Biol Blood Marrow Transplant.* 2018;24(6):1135-1141. **2.** Dave H, Jerkins L, Hanley PJ, Bollard CM, Jacobsohn D. Driving the CAR to the bone marrow transplant program. *Curr Hematol Malig Rep.* 2019;14(6):561-569. **3.** Wang X, Rivière I. Clinical manufacturing of CAR T cells: foundation of a promising therapy. *Mol Ther Oncolytics.* 2016;3:16015. **4.** Beaupierre A, Lundberg R, Marrero L, Jain M, Wang T, Alencar MC. Management across settings: an ambulatory and community perspective for patients undergoing CAR T-cell therapy in multiple care settings. *Clin J Oncol Nurs.* 2019;23(2):27-34. **5.** National Cancer Institute. CAR T-cell therapy. Accessed January 30, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy **6.** June CH, Sadelain M. Chimeric antigen receptor therapy. *N Engl J Med.* 2018;379(1):64-73.

The CAR-T treatment process (more)

STEP 4: ONE-TIME CAR-T INFUSION

- You'll receive CAR-T cells through a one-time intravenous (IV) infusion

Your healthcare team at the Certified Treatment Center will prepare you for your infusion day.

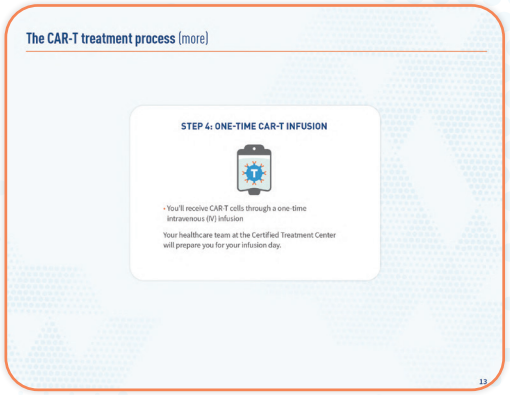
The CAR-T treatment process (more)

KEY TAKEAWAY

- Step 4 involves a one-time CAR-T infusion[1-6]

TALKING POINTS

- **STEP 4—ONE-TIME CAR-T INFUSION[1-7]**
  - About a month after your initial cell collection and following lymphodepletion, you'll be given your CAR-T cells through a one-time intravenous infusion
  - Your healthcare team at the Certified Treatment Center will guide you through what your infusion day will be like and how to prepare



Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Preparations for the CAR-T infusion
- Number of CAR-T infusions

References: 1. Abecma® (idecabtagene vicleucel). Prescribing Information. Bristol-Myers Squibb Company; 2021. **2.** Breyanzi® (lisocabtagene maraleucel). Prescribing Information. Summit, NJ: Bristol-Myers Squibb Company; 2022. **3.** CARVYKTI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **4.** Kymriah® (tisagenlecleucel). Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2022. **5.** Yescarta® (axicabtagene ciloleucel). Prescribing Information. Kite Pharma, Inc; 2022. **6.** Tecartus® (brexucabtagene autoleucel). Prescribing Information. Kite Pharma, Inc; 2021.**7.** Beaupierre A, Kahle N, Lundberg R, Patterson A. Educating multidisciplinary care teams, patients, and caregivers on CAR T-cell therapy. *J Adv Pract Oncol.* 2019;10(suppl 3):29-40.

The CAR-T treatment process (more)

STEP 5: MONITORING

SHORT-TERM MONITORING

- The Certified Treatment Center will monitor you closely for side effects after the infusion of your CAR-T cells
- After treatment, you'll need to stay near the Certified Treatment Center at least 4 weeks (timing may vary depending on patient and product)
- The healthcare team will partner with your primary oncology team to provide ongoing care and assessment

LONG-TERM FOLLOW-UP AND MONITORING

- Medical care and monitoring continue after the short-term monitoring period
- You may be able to return home and resume care with your primary oncologist depending on the decision of the healthcare team
- Always inform your healthcare team and primary oncologist about how you are feeling

The CAR-T treatment process (more)

KEY TAKEAWAY

- Step 5 involves 2 phases: short- and long-term monitoring

TALKING POINTS

- **STEP 5—SHORT-TERM MONITORING[1]**
  - Your healthcare team at the Certified Treatment Center will monitor you after the infusion of your CAR-T cells
  - Plan to stay near the Certified Treatment Center for at least 4 weeks (timing may vary depending on patient and product)
  - Many of the side effects may require quick medical attention
- **STEP 5—LONG-TERM MONITORING[1,2]**
  - You'll continue to be under medical care and monitored by your primary healthcare team and primary oncologist after the short-term period
  - Depending on the decision of your CAR-T healthcare team, you may be able to return home and resume care with your primary oncologist
  - Be sure to let your primary healthcare team and primary oncologist know if any symptoms arise or if you're not feeling well, to help ensure they can manage your care appropriately

Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Staying at the Certified Treatment Center
- Monitoring after CAR-T infusion

References: 1. Beaupierre A, Kahle N, Lundberg R, Patterson A. Educating multidisciplinary care teams, patients, and caregivers on CAR T-cell therapy. *J Adv Pract Oncol.* 2019;10(suppl 3):29-40. **2.** Beaupierre A, Lundberg R, Marrero L, Jain M, Wang T, Alencar MC. Management across settings: an ambulatory and community perspective for patients undergoing CAR T-cell therapy in multiple care settings. *Clin J Oncol Nurs.* 2019;23(2):27-34.

Potential side effects

ARE THERE ANY SIDE EFFECTS?

- Patients can experience certain reactions to CAR-T cells that can be severe or life-threatening
- Serious side effects of CAR-T therapy include:
  - Cytokine release syndrome (CRS)
  - Neurologic side effects, known as neurologic toxicity
  - Low blood cell counts, known as cytopenias
  - Low antibody counts, known as hypogammaglobulinemia
  - Serious infections
- These are not all the side effects that you may experience. Other side effects can occur as well. It is important to speak with your doctor and treatment team about how you are feeling and if you think you are having any side effects

CALL YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP RIGHT AWAY IF YOU EXPERIENCE ANY OF THESE SYMPTOMS

Because of the risk of CRS and neurologic toxicity, CAR-T therapy is available only through restricted programs under a Risk Evaluation and Mitigation Strategy (REMS). The healthcare team at each Certified Treatment Center must be trained in recognizing and managing CRS and neurologic toxicity and have appropriate treatments available on-site to help manage these symptoms.

THERE WILL BE A TRAINED HEALTHCARE TEAM SUPPORTING YOU

- CAR-T treatment is administered within a Certified Treatment Center by a specialized healthcare team
- Patients are monitored by staff who are trained to manage the side effects associated with CAR-T therapies
- Discuss the potential risks of treatment with your doctor

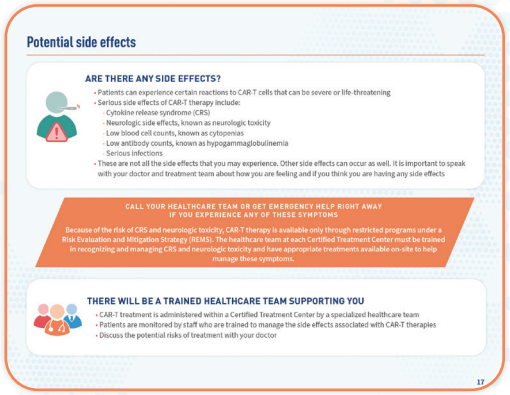
Potential side effects

KEY TAKEAWAYS

- Reactions to CAR-T cells can be severe or life-threatening[1]
- CAR-T therapy is administered by a specialized healthcare team qualified to manage these serious side effects[2]

TALKING POINTS

- Patients can experience certain side effects to CAR-T therapy that can or may be severe or life-threatening. This is why you'll need to stay at or near the Certified Treatment Center where you received your CAR-T infusion at least 4 weeks (timing may vary depending on patient and product)[1,2]
- Serious side effects include[2-8]:
  - Cytokine release syndrome (CRS), which can cause fever, rapid heart rate, low blood pressure, and other symptoms
  - Neurologic toxicity, which can cause confusion, tremors, difficulty with motor function, or difficulty with communication
  - Prolonged cytopenias, which are a reduction of cells circulating in the blood for an extended period of time
  - Hypogammaglobulinemia, which is when the amount of antibodies in blood is low, increasing risk of infection
  - Serious infections, which can develop into life-threatening infections
  - Because of the risk of CRS and neurologic toxicity, CAR-T therapy is available only through restricted programs under a REMS
- CAR-T therapies are available only at Certified Treatment Centers where the healthcare teams are trained in recognizing and managing serious side effects related to the infusion treatment[9]



Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Monitoring for signs and symptoms after infusion
- Side effect management

References: 1. Beaupierre A, Kahle N, Lundberg R, Patterson A. Educating multidisciplinary care teams, patients, and caregivers on CAR T-cell therapy. *J Adv Pract Oncol.* 2019;10(suppl 3):29-40. **2.** Beaupierre A, Lundberg R, Marrero L, Jain M, Wang T, Alencar MC. Management across settings: an ambulatory and community perspective for patients undergoing CAR T-cell therapy in multiple care settings. *Clin J Oncol Nurs.* 2019;23(2):27-34. **3.** Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. *Biol Blood Marrow Transplant.* 2019;25(4):625-638. **4.** National Cancer Institute. Cytokine release syndrome. Accessed January 31, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cytokine-release-syndrome **5.** Brudno JN, Kochenderfer JN. Recent advances in CAR T-cell toxicity: mechanisms, manifestations and management. *Blood Rev.* 2019;34:45-55. **6.** National Institute of Neurological Disorders and Stroke. Neurotoxicity. Accessed January 31, 2023. https://www.ninds.nih.gov/health-information/disorders/neurotoxicity#:~:text=Definition **7.** Alpert N, Rapp JL, Mascarenhas J, et al. Prevalence of cytopenia in the general population—a national health and nutrition examination survey analysis. *Front Oncol.* 2020;10:579075. **8.** National Cancer Institute. Cytopenia. Accessed January 31, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cytopenia **9.** National Cancer Institute. Hypogammaglobulinemia. Accessed January 31, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/hypogammaglobulinemia

Importance of caregiver support

CAREGIVERS PLAY AN IMPORTANT ROLE

- A friend or family member will be needed to help provide support throughout the CAR-T treatment process
  - Monitoring and tracking signs or symptoms of side effects
  - Scheduling appointments
  - Providing transportation to appointments
  - Managing your schedule
  - Helping communicate with your healthcare team
  - Calling your doctor
  - Taking care of responsibilities
  - Offering support
- Caregivers play an important role by advocating for the person they are caring for. If they have any questions about treatment, they can ask a member of the healthcare team. The doctors and nurses expect you to have questions, and they know that helping support you is an important part of a successful treatment
- Certain tasks that you might be accustomed to doing yourself will require support. Driving a car and other activities that require alertness should be avoided after receiving treatment

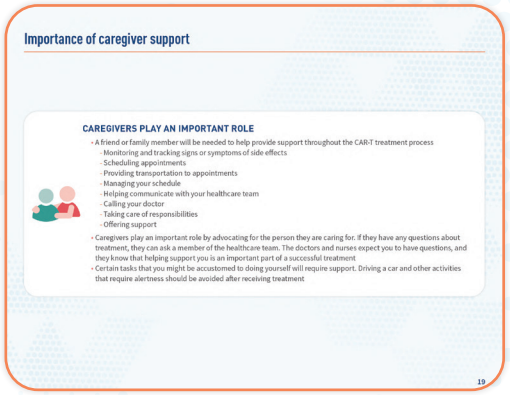
Importance of caregiver support

KEY TAKEAWAY

- It's essential that patients have a friend or family member to help with their care

TALKING POINTS[1,2]

- You will need a friend or family member to help with your care and help to provide support through the CAR-T treatment process
  - Monitoring and tracking signs or symptoms of side effects
  - Scheduling appointments
  - Providing transportation to appointments and keeping you company
  - Managing your schedule and letting visitors know when you do or don't feel up to seeing them
  - Helping communicate with your healthcare team (for example, sharing health details, providing insurance information, asking questions)
  - Calling your doctor if you're not feeling well
  - Taking care of responsibilities at home
  - Offering support and being there to talk
- Treatment can cause certain side effects that can impact your abilities to drive or do any other activities that require alertness. After receiving treatment, you should have a caregiver assist you with these activities



Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Follow-up with caregiver
- Restrictions after CAR-T infusion

References: 1. Beaupierre A, Kahle N, Lundberg R, Patterson A. Educating multidisciplinary care teams, patients, and caregivers on CAR T-cell therapy. *J Adv Pract Oncol.* 2019;10(suppl 3):29-40. **2.** Beaupierre A, Lundberg R, Marrero L, Jain M, Wang T, Alencar MC. Management across settings: an ambulatory and community perspective for patients undergoing CAR T-cell therapy in multiple care settings. *Clin J Oncol Nurs.* 2019;23(2):27-34.

Glossary

CAR (chimeric antigen receptor)—a receptor that is genetically modified in your T cells at a specialized facility to identify cancer cells.

CAR-T cells—T cells that have been genetically modified in a specialized facility to effectively identify targets on cancer cells in order to hook onto the targets and destroy them.

CAR-T therapy—a cancer treatment in which your own 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 life-threatening or even fatal condition in which your body reacts to the CAR-T cell infusion by releasing cytokines, a type of immune cell.

Leukapheresis (loo-kah-fur-ee-sis)—the first step of the CAR-T treatment process. In it, some of your blood is collected and passed through a machine that separates some of your white blood cells (including T cells), and 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 specialized facility, where they will be used to make your unique CAR-T cells.

Lymphodepletion—to prepare your body to receive CAR-T cells, you will be given infusions of low-dose chemotherapy daily for several days. This treatment reduces the number of white blood cells in your body, giving the CAR-T cells room to multiply once they are returned to your body. This step in the CAR-T treatment process takes place a few days before your infusion of CAR-T cells.

Neurologic toxicity—a side effect that happens when exposure to a substance (such as a medical treatment) changes the normal activity of the brain or nervous system. This can happen from changes to the way signals are transmitted and processed in the brain and other parts of the nervous system.

T cells—cells that patrol the body for signs of infection and diseases, and initiate a response to destroy both.

Glossary

CAR (chimeric antigen receptor)—a receptor that is genetically modified in the patient's T cells at a specialized facility to identify cancer cells.[1-3]

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Neurologic toxicity—a side effect that happens when exposure to a substance (such as a medical treatment) changes the normal activity of the brain or nervous system. This can happen from changes to the way signals are transmitted and processed in the brain and other parts of the nervous system.[11]

T cells—cells that patrol the body for signs of infection and diseases, and initiate a response to destroy both.[12]

References: 1. National Cancer Institute. CAR T-cell therapy. Accessed January 31, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy **2.** Bonifant CL, Jackson HJ, Brentjens RJ, Curran KJ. Toxicity and management of CAR T-cell therapy. *Mol Ther Oncolytics.* 2016;3:16011. **3.** Belin C, Devic P, Ayrignac X, et al. Description of neurotoxicity in a series of patients treated with CAR T cell therapy. *Sci Rep.* 2020;10(1):18997. **4.** Majzner RG, Mackall CL. Clinical lessons learned from the first leg of the CAR T cell journey. *Nat Med.* 2019;25(9):1341-1355. **5.** National Cancer Institute. Cytokine release syndrome. Accessed January 31, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cytokine-release-syndrome **6.** National Cancer Institute. Leukapheresis. Accessed January 31, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/leukapheresis **7.** Wang X, Rivière I. Clinical manufacturing of CAR T cells: foundation of a promising therapy. *Mol Ther Oncolytics.* 2016;3:16015. **8.** Beaupierre A, Lundberg R, Marrero L, Jain M, Wang T, Alencar MC. Management across settings: an ambulatory and community perspective for patients undergoing CAR T-cell therapy in multiple care settings. *Clin J Oncol Nurs.* 2019;23(2):27-34. **9.** Perica K, Curran KJ, Brentjens RJ, Giralt SA. Building a CAR garage: preparing for the delivery of commercial CAR T products at Memorial Sloan Kettering Cancer Center. *Biol Blood Marrow Transplant.* 2018;24(6):1135-1141. **10.** ClinicalTrials.gov. Leukapheresis for CAR or Adoptive Cell Therapy Manufacturing. ClinicalTrials.gov Identifier: NCT03226704. Updated January 10, 2023. Accessed January 31, 2023. https://clinicaltrials.gov/ct2/show/NCT03226704 **11.** National Institute of Neurological Disorders and Stroke. Neurotoxicity. Accessed January 31, 2023. https://www.ninds.nih.gov/health-information/disorders/neurotoxicity#:~:text=Definition **12.** National Cancer Institute. T cell. Accessed January 31, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/t-cell

Questions to ask your healthcare providers

WORK WITH YOUR PHYSICIAN TO DETERMINE IF CAR-T THERAPY IS RIGHT FOR YOU

Remember that your healthcare providers are there to assist you during every step of the treatment process. If you have any questions about your treatment, do not hesitate to ask a member of the team.

COMMONLY ASKED QUESTIONS

Here are examples of questions you may want to ask as you discuss CAR-T therapy.

- How should I prepare for CAR-T therapy?
- How is CAR-T therapy different from other types of cancer treatment?
- How is the patient experience of CAR-T therapy different from stem cell transplant (SCT)?
- How does the recovery period after CAR-T infusion differ from SCT?
- Is CAR-T therapy covered by my insurance?
- Is there financial support for travel costs for people receiving CAR-T therapy?
- Are there any services or resources that help with practical or emotional support?

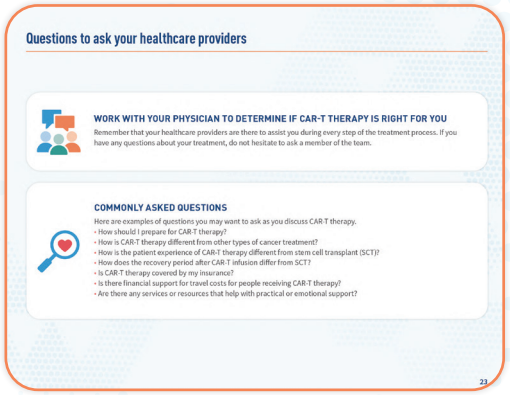
Questions to ask healthcare providers

KEY TAKEAWAY

- Determining if CAR-T therapy is right for a person is a collaborative process. Asking questions is an important way to participate in the CAR-T treatment decisions

TALKING POINTS

- Below and on previous pages are examples of common topics that you may ask about CAR-T therapy
- You may want to better understand the differences between CAR-T therapy and other treatment options, such as SCT
- The answers to some questions could be specific to you or to the Certified Treatment Center



Patient View

PATIENTS MAY ASK QUESTIONS ABOUT TOPICS SUCH AS:

- Preparing for CAR-T therapy
- Difference between CAR-T therapy and other cancer treatments
- Difference between CAR-T therapy and SCT
- Difference in recovery period for CAR-T infusion and SCT
- Insurance coverage for CAR-T therapy
- Financial support for travel costs associated with CAR-T therapy
- Additional support services and resources for patients

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