Idecabtagene Vicleucel

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for multiple myeloma (MM).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment is typically given as a 1-time dose.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Idecabtagene vicleucel (I-deh-KAB-tuh-jeen vik-LOO-sel): Abecma (uh-BEK-muh) This treatment is also called “ide-cel”.	Idecabtagene vicleucel is a chimeric antigen receptor T-cell (CAR-T) therapy. CAR-T therapy uses your own white blood cells to fight your cancer. Some of your white blood cells are removed from your blood and sent to a lab, where they are "reprogrammed" to find and track your specific cancer cells. Once these cells are infused back into your body, they hunt down the cancer and work to destroy it.	Infusion given into a vein (intravenous (IV) infusion).

Treatment Administration and Schedule

- Since your treatment is made from your own white blood cells, your care team has to take some of your blood. This is called "leukapheresis." It takes 3 to 6 hours and may need to be repeated. A tube (intravenous catheter) will be placed in your vein to collect your blood.
- Your blood cells are frozen and sent to the manufacturing site to make idecabtagene vicleucel. It takes about 4 weeks from the time your cells are received at the manufacturing site until they are shipped back to your care team, but the time may vary.
- While waiting for idecabtagene vicleucel to be made, your care team may give you therapy to stabilize your cancer.
- In addition, before you get idecabtagene vicleucel, your care team may give you chemotherapy for a few days to prepare your body.
- When your body is ready, your care team will give you idecabtagene vicleucel through a tube (intravenous catheter) in your vein.
- You should plan to stay close to a healthcare facility for at least 1 week after getting idecabtagene vicleucel. Your care team will check whether your treatment is working and help you with any side effects.

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Appointments

Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help lower the risk of Cytokine Release Syndrome (CRS)		
To help prevent or treat nausea and vomiting		
To help lower the risk of infections		
Other		

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Common Side Effects

Side Effect	Important Information
Cytokine Release Syndrome (CRS) (Boxed Warning)	Description: CRS happens when your immune system becomes overactive. Some CRS events can be serious and life-threatening. Symptoms can include fever, chills, fatigue, headache, dizziness or feeling lightheaded, or difficulty breathing. Recommendations: • Keep a symptom diary to record any new or worsening symptoms such as fever, chills, fatigue, or difficulty breathing. • Check vital signs regularly, including temperature, blood pressure, blood oxygen levels (blood oxygen saturation), and heart rate. • Stay hydrated by drinking plenty of fluids to help manage symptoms and support overall health. • Your care team may prescribe medications for CRS. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Trouble breathing • Chills • Dizziness or light-headedness • Fast heartbeat • Headache Note: Your care team may have specific numbers for blood pressure, heart rate, and blood oxygen levels. If your numbers go beyond those limits, call your care team or get emergency help.
Neurologic Problems, Including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (Boxed Warning)	Description: Treatment can cause neurologic problems that can be serious or life-threatening. You may have symptoms such as confusion, difficulty speaking, mood changes, headaches, seizures, and weakness. Recommendations: • Keep a symptom diary to track any changes in behavior, mood, or cognitive function. • Your care team or caregiver will regularly check how your brain is working by performing an “ICE score”. The ICE score is a 10-point check of your thinking, talking, and writing to see if your treatment is affecting your brain. • Monitor for neurologic symptoms such as confusion, difficulty speaking, weakness, or seizures. • Your care team may prescribe medicine for neurologic problems. Talk to your care team if you have: • Headache • Agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real (hallucinations) • Trouble speaking, writing, thinking, remembering things, paying attention, or understanding things • Problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms • Numbness and tingling (feeling like "pins and needles") • Burning, throbbing, or stabbing pain • Changes in your handwriting • Seizures

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Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)	Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection. It can sometimes take a long time for your WBCs to recover. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Platelet Count (Thrombocytopenia) (Boxed Warning)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. It can sometimes take a long time for your platelets to recover. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Talk with your care team or dentist before medical or dental procedures. Talk to your care team if you have: • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Sudden or severe headache • Blood in your urine or stool • Blood in your spit after coughing
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia) (Boxed Warning)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak, very tired, or look pale. It can sometimes take a long time for your RBCs and Hgb to recover. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

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<td>Low Immunoglobulin Levels (Hypogammaglobulinemia)</td>
<td>Description: Hypogammaglobulinemia means low antibody (immunoglobulin) levels in your blood. This makes it harder for your body to fight infections and can lead to more frequent or severe infections.
Recommendations:
Wash your hands often and avoid close contact with people who are sick.
Tell your care team about any recent or frequent infections, and follow their infection prevention plan.
Your care team may monitor antibody levels, give immunoglobulin replacement, or prescribe preventive antibiotics or other anti-infective medicines. Take these exactly as directed.
Talk to your care team if you have:
Getting sick often (like colds or pneumonia)
Taking longer to feel better after being sick
Tiredness or weakness
Skin infections or rashes
Severe stomach-area (abdominal) pain or diarrhea
New or worsening allergies or other immune problems</td>
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<td>Nausea and Vomiting</td>
<td>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.
Recommendations:
Eat smaller, more frequent meals.
Avoid fatty, fried, spicy, or highly sweet foods.
Eat bland foods at room temperature and drink clear liquids.
If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods.
Your care team may prescribe medicine for these symptoms.
Talk to your care team if you have:
Vomiting for more than 24 hours
Nonstop vomiting
Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)
Blood or coffee-ground-like appearance in your vomit
Severe stomach pain that does not go away after vomiting</td>
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Diarrhea	Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness. Recommendations: • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). Talk to your care team if you have: • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Risk of New Cancers (Boxed Warning)	There is a risk of developing new cancers, such as T-cell malignancies, during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms of new cancers.
CAR T-Associated Hemophagocytic Lymphohistiocytosis (HLH) (Boxed Warning)	CAR T-cell-associated HLH or Immune Effector Cell-Associated HLH-like Syndrome (IEC-HS) is a rare, life-threatening complication where the CAR T-cells trigger a massive, uncontrolled wave of inflammation that attacks the body's own organs. It is essentially an extreme overreaction of the immune system that can occur shortly after treatment or as a "second wave" of illness following cytokine release syndrome. • High fevers that do not go away • New or worsening bruising or unusual bleeding • Extreme tiredness or weakness • Yellowing of your skin or the whites of your eyes (jaundice) • Severe pain or swelling in your abdomen (stomach area) • Confusion, dizziness, or changes in your mental state • Difficulty breathing or shortness of breath
Allergic Reactions	Serious allergic reactions, including anaphylaxis, which is a life-threatening allergic reaction, may occur after you receive idecabtagene vicleucel. Get emergency medical help right away if you develop any of the following signs or symptoms: • Difficulty breathing • Very low blood pressure • Dizziness • Swelling under skin • Rash • Nausea • Vomiting
Hepatitis B Virus (HBV) Reactivation	Before you receive idecabtagene vicleucel, your care team will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of hepatitis B virus, receiving idecabtagene vicleucelcould cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems, including liver failure and death. Your care team will monitor you for hepatitis B infection during and for several months after you receive idecabtagene vicleucel. • Worsening tiredness • Yellowing of your skin or white part of your eyes
Cytomegalovirus (CMV) Reactivation	Before you receive idecabtagene vicleucel, your care team may do blood tests to check for CMV. If you have had CMV in the past, receiving idecabtagene vicleucel could cause the virus to become active again. CMV reactivation may cause serious organ problems (for example, lung, liver, gut, or eye disease) and can be life-threatening in people with weakened immune systems. Your care team will monitor you for CMV infection during treatment and for several months after treatment. • Fever or chills • New cough or shortness of breath • Severe stomach-area (abdominal) pain, diarrhea, or vomiting • Yellowing of skin or dark urine • New vision changes or eye pain • Unexplained severe tiredness or weakness

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Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Tell your care team if you are **pregnant, planning to be pregnant, or breastfeeding**. Your care team may do a pregnancy test prior to your starting treatment. No information is available for idecabtagene vicleucel use in pregnant or breastfeeding people. Therefore, idecabtagene vicleucelis not recommended for people who are pregnant or breastfeeding. Talk to your care team about birth control and pregnancy.

Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
    - You should not receive a live vaccine 6 weeks before the start of lymphodepleting chemotherapy, during treatment with idecabtagene vicleucel, and until your immune system recovers after treatment. Talk with your care team if you have questions about whether a vaccine is a live vaccine.
- **Avoid driving** for at least 1 week after you get idecabtagene vicleucel.
- **Do not donate blood, organs, tissues, sperm, oocytes**, and other cells after treatment with idecabtagene vicleucel.
- Some commercial HIV tests may cause a **false positive HIV test result**.
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.

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