
Child portrayed is not a real KYMRIAH patient.

**DISCUSSION GUIDE**

# What should I ask my treatment team?

Making treatment decisions for relapsed or refractory cancer can be hard. Asking questions along the way can help make things easier. Be sure to talk with your treatment team about any questions or concerns you may have about KYMRIAH® (tisagenlecleucel). Refer to this list at any step of the process to help guide your discussions and use the space available to take notes.

## IMPORTANT INFORMATION

### What is KYMRIAH?

KYMRIAH is a prescription cancer treatment used in patients up to 25 years old who have acute lymphoblastic leukemia (ALL) that has relapsed (went into remission, then came back) or is refractory (did not go into remission with other leukemia treatments). KYMRIAH is made from your own white blood cells.

### What is the most important information I should know about KYMRIAH?

KYMRIAH may cause side effects that are severe or life-threatening, such as cytokine release syndrome (CRS) and neurological toxicities. Call your health care provider or get emergency help right away if you get any of the following signs and symptoms of:

- **Cytokine Release Syndrome:**
  - difficulty breathing
  - fever (100.4°F/38°C or higher)
  - chills/shaking chills
  - severe nausea, vomiting, diarrhea
  - severe muscle or joint pain
  - very low blood pressure
  - dizziness/lightheadedness

**Please see additional important safety information throughout and Summary of Important Information on pages 4 to 5.**

## 1 Initial Discussion

- How does my treatment history affect my eligibility for KYMRIAH® (tisagenlecleucel)?
- Can I receive KYMRIAH after a bone marrow transplant?
- What if I have other health conditions?
- How will I feel throughout the treatment process?

## 2 Find a KYMRIAH Treatment Center

- Where can I receive KYMRIAH therapy?
- Will my insurance cover KYMRIAH therapy?
- How long will I need to stay near the treatment center?

## 3 Collection

- How should I prepare for collection?
- How long will it take?
- What can I do during collection?
- Will there be any limitations or side effects afterward?
- When will my KYMRIAH chimeric antigen receptor (CAR) T cells cells be ready for infusion?

**Notes:**

**IMPORTANT INFORMATION** (continued)

**What is the most important information I should know about KYMRIAH?** (continued)

Call your health care provider or get emergency help right away if you get any of the following signs and symptoms of:

- **Neurological Toxicities:**
  - altered or decreased consciousness
  - delirium
  - confusion
  - agitation
  - seizures
  - difficulty speaking and understanding
  - loss of balance

You may be admitted to the hospital, and treated with other medications, if you have CRS. If you are admitted to the hospital, tell the health care provider that you have received KYMRIAH.

Because of the risk of CRS, and neurological toxicities, KYMRIAH is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS.

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KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

## 4 Preinfusion Lymphodepleting Chemotherapy

- How is this chemotherapy different from the chemotherapy I previously received?
- How long will it take?
- Will there be side effects?
- How far in advance of my infusion do I receive chemotherapy?

## 5 Infusion

- How should I prepare for infusion?
- What will infusion be like?
- How long will it take?

## 6 Side Effects and Observation

- What side effects should I expect after infusion?
- How will serious side effects be managed after therapy?
- How will I know KYMRIAH® (tisagenlecleucel) is working?
- When do I need to check in with my treatment team?
- How long do I need to stay in or near my hospital?
- After returning home, what kind of side effects require a hospital visit?
- How quickly can I get back to my daily routine?

**Notes:**

**IMPORTANT INFORMATION** (continued)

**What are other serious side effects of KYMRIAH?**

- **Allergic Reactions:** Serious allergic reactions, including anaphylaxis, which is a life-threatening allergic reaction, may occur after you receive KYMRIAH. Some signs and symptoms may include difficulty breathing, very low blood pressure, dizziness, swelling under skin, rash, nausea, and vomiting. You should seek emergency medical treatment right away if you have an allergic reaction.
- **Serious Infections:** KYMRIAH can increase the risk of life-threatening infections that may lead to death. Tell your health care provider right away if you develop fever, chills, or any signs or symptoms of an infection.

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KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

## Summary of Important Information

**What is KYMRIAH?**

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**What is the most important information I should know about KYMRIAH?**

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  - chills/shaking chills
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- **Serious Infections:** KYMRIAH can increase the risk of life-threatening infections that may lead to death. Tell your health care provider right away if you develop fever, chills, or any signs or symptoms of an infection.
- **Prolonged Low Blood Cell Counts (Cytopenia):** KYMRIAH can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets). After treatment, your health care provider may test your blood to check cell counts. Tell your health care provider right away if you get a fever or other symptoms of an infection, are feeling tired, or have unusual bruising or bleeding.
- **Hypogammaglobulinemia:** A condition in which the level of immunoglobulins (antibodies) in your blood is low and the risk of infection is increased. It is expected that you may develop hypogammaglobulinemia with KYMRIAH, and you may need to receive immunoglobulin replacement for an indefinite amount of time following treatment with KYMRIAH. Tell your health care provider about your treatment with KYMRIAH before receiving a live virus vaccine.
- **Secondary Cancers:** After treatment with KYMRIAH, your health care provider will monitor you for the rest of your life, as you may develop secondary cancers or recurrence of your leukemia.
- **Effects on Ability to Drive and Use Machines:** Do not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get KYMRIAH because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures.

## Summary of Important Information (continued)

**What are the most common side effects of KYMRIAH?**

Some of the most common side effects of KYMRIAH® (tisagenlecleucel) include:

- difficulty breathing
- fever (100.4°F/38°C or higher)
- chills/shaking chills
- confusion
- severe nausea, vomiting, diarrhea
- severe muscle or joint pain
- very low blood pressure
- dizziness/lightheadedness
- headache

These are not all the possible side effects of KYMRIAH. Talk to your health care provider for medical advice about side effects.

**What should I tell my health care provider before receiving KYMRIAH?**

- Your health care provider may do a pregnancy test prior to you starting treatment. There is no information available of KYMRIAH use in pregnant or breastfeeding women. Therefore, KYMRIAH is not recommended for women who are pregnant or breastfeeding. Talk to your health care provider about birth control and pregnancy.
- Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**What should I be aware of after receiving KYMRIAH?**

- Some commercial HIV tests may cause a false positive HIV test result
- Do not donate blood, organs, tissues or cells for transplantation

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This is a summary of the most important safety information about KYMRIAH. Talk with your health care provider or pharmacist about side effects. If you would like more information, the FDA-approved product labeling for KYMRIAH can be found at www.KYMRIAH.com, or call 1-844-NVS-CART (1-844-687-2278).

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