Patient Information

CASGEVY® (cass-JEH-vee)

(exagamglogene autotemcel)

suspension for intravenous infusion

This leaflet is written for you or your child. In this leaflet, "you" refers to you or your child.

What is the most important information I should know about CASGEVY?

After treatment with CASGEVY you will have fewer blood cells for a while, until CASGEVY takes hold (*engrafts*) into your bone marrow. This includes low levels of platelets (cells that usually help the blood to clot) and white blood cells (cells that usually fight infections). Your healthcare provider will monitor this and give you treatment as required. The healthcare provider will tell you when blood cell levels return to safe levels.

- **Tell your healthcare provider right away** if you experience any of the following, which could be signs of low levels of platelet cells:
  - severe headache
  - abnormal bruising
  - prolonged bleeding
  - bleeding without injury such as nosebleeds, bleeding from gums, blood in your urine, stool, or vomit, or coughing up blood.

- **Tell your healthcare provider right away** if you experience any of the following, which could be signs of low levels of white blood cells:
  - fever
  - chills
  - infections

You may experience side effects associated with other medicines administered as part of the CASGEVY treatment regimen. Talk to your healthcare provider regarding those possible side effects. Your healthcare provider may give you other medicines to treat your side effects.

What is CASGEVY?

CASGEVY is a one-time therapy used to treat people aged 2 years and older with:

- sickle cell disease (SCD) who have frequent vaso-occlusive crises or VOCs
- beta-thalassemia (β-thal) who need regular blood transfusions.

CASGEVY is made specifically for each patient, using the patient's own edited blood stem cells, and increases the production of a special type of hemoglobin called hemoglobin F (fetal hemoglobin or HbF). Having more HbF increases overall hemoglobin levels and has been shown to improve the production and function of red blood cells. This can eliminate VOCs in people with sickle cell disease and eliminate the need for regular blood transfusions in people with β-thalassemia.

How will I receive CASGEVY?

Your healthcare provider will give you other medicines, including a *chemotherapy* medicine, as part of your treatment with CASGEVY. It's important to talk to your healthcare provider about the risks and benefits of all medicines involved in your treatment.

After receiving the *chemotherapy* medicine, it may not be possible for you to become pregnant or father a child. You should discuss options for fertility preservation with your healthcare provider before treatment.

CASGEVY is made specifically for you from your own blood stem cells. Receiving CASGEVY is a multi-step process:

- Your healthcare provider will collect your blood stem cells through a process called mobilization and apheresis. This process may happen more than once. Each time, it can take up to one week.

- Back-up cells are also collected and stored at the hospital. These are kept and maybe given to you in case there is a problem in the treatment process. If you receive back-up cells, you will not have any benefit from CASGEVY.

- Your collected blood stem cells will be sent to the manufacturing site where they are used to make CASGEVY. Manufacturing may take up to 6 months.

- Shortly before you receive CASGEVY, you will be admitted to the hospital. Your healthcare provider will give you *chemotherapy* medicine for a few days to make room in the bone marrow for your edited stem cells. After you are given this medicine, your blood cell levels will fall to very low levels.

- One or more vials of CASGEVY will be given into a vein (*intravenous infusion)*.

- After the CASGEVY infusion, you will stay in hospital so that your healthcare provider can closely monitor your recovery. This can take 4-6 weeks, but times can vary. Your healthcare provider will decide when you can go home.

What should I avoid after receiving CASGEVY?

- Do not donate blood, organs, tissues, or cells at any time in the future.

What are the possible or reasonably likely side effects of CASGEVY?

The most common side effects of CASGEVY include:
- Low levels of platelet cells, which may reduce the ability of blood to clot and may cause bleeding.
- Low levels of white blood cells, which may make you more susceptible to infection.

Your healthcare provider will test your blood to check for low levels of blood cells (including platelets and white blood cells). Tell your healthcare provider right away if you get any of the following symptoms:
- fever
- chills
- infections
- severe headache
- abnormal bruising
- prolonged bleeding
- bleeding without injury such as nosebleeds, bleeding from gums, blood in your urine, stool, or vomit, or coughing up blood.

These are not all the possible side effects of CASGEVY. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of CASGEVY

Talk to your healthcare provider about any health concerns. You can ask your healthcare provider for information about CASGEVY that is written for healthcare professionals.

For more information, go to Casgevy.com or call 1-833-837-8395.

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