

Could LYFGENIA Be a Part of *Your Next Chapter?*

For people living with sickle cell disease, or their caregivers, who are actively considering gene therapy with LYFGENIA, this guide will help you **assess if medical, lifestyle, and support needs are in place for treatment.**

Big decisions start with small steps. Begin your checklist.

Let's Start With the Basics

Treatment eligibility and planning both include many factors, and it's best to be sure that you and your care team are on the same page. The following are eligibility requirements for gene therapy with LYFGENIA:

Confirmed diagnosis of sickle cell disease

12 years of age or older

A history of vaso-occlusive events (VOEs)* also known as sickle cell crises

Your doctor has confirmed you are physically able to undergo gene therapy



This guide can support, but not replace, conversations with your healthcare team.
Talk to your doctor about questions related to gene therapy, including potential risks, benefits, and long-term considerations.

*Vaso-occlusive events (VOEs) were defined as any of the following events requiring evaluation at a medical facility: an episode of acute pain with no medically determined cause other than vaso-occlusion lasting more than 2 hours, acute chest syndrome, acute hepatic sequestration, or acute splenic sequestration.

What is LYFGENIA?

LYFGENIA is a one-time gene therapy to treat sickle cell disease in patients 12 years of age or older and a history of vaso-occlusive events. LYFGENIA is made specifically for each patient, using the patient's own blood stem cells (from which red blood cells are produced). It adds functional copies of the beta-globin gene to your cells leading to production of anti-sickling hemoglobin that may decrease or stop vaso-occlusive events.

Important Safety Information

What is the most important safety information I should know about LYFGENIA?

At the time of initial FDA approval, three patients were diagnosed with blood cancer. Two patients were treated with an earlier version of LYFGENIA using a different manufacturing process and transplant procedure and one patient had α -thalassemia trait.

Treatment with LYFGENIA may increase your risk of developing blood cancer, which can be life-threatening and/or cause death and can develop many years after treatment with LYFGENIA. Because of this risk, it is important for you to be monitored at least every 6 months for a minimum of 15 years after LYFGENIA.

Please see additional [Important Safety Information](#) and [full Prescribing Information](#), including **Boxed WARNING** and [Medication Guide](#) for LYFGENIA.


lyfgenia[™]
(lovotibeglogene autotemcel)
suspension for IV infusion

LYFGENIA Treatment: *So, What's Involved?*

Disease History & Current Treatments: Your Story So Far

Your real-life experience matters. Think about how sickle cell disease has affected you and your loved ones to help determine if now is the time for a different treatment approach:

- Have experienced sickle cell crises that affect daily life
- School, work, or plans have been disrupted due to managing a sickle cell crisis
- Current treatments have not reduced or stopped sickle cell crises or controlled the disease enough
- Regular transfusions or other disease-modifying therapies are needed

Making a Plan & Building Your Support System

While LYFGENIA is a one-time gene therapy treatment, it's not something you do alone. Taking time to consider your daily life and the support you may need can help you feel ready for the journey ahead. Think about the effect on your daily responsibilities when you are away. Have you:

- Considered what taking time away from school or work would look like
- Identified main responsibilities that may be affected and who may help cover them
- Planned for a gradual return to work or school, with extra time if needed

Treatment can take time and impact you in other ways, not just physically. Do you:

- Have people to talk to about stress, fear, and uncertainty
- Feel comfortable asking for help
- Speak about emotional readiness with your care team
- Know who will be part of your personal support system at the treatment center

There's no one "right" way to build support. It might be one main caregiver, a few people sharing responsibilities, or even regular calls and texts that help you feel supported throughout the whole process.

Recovery will take time, and you may need support through the process. Have you:

- Considered that you may need a caregiver or other support during recovery
- Identified someone for ongoing support and discussed time commitment and logistics
- Made a plan for who would help with your care once you're home after treatment

You may need to consider fertility and family planning. Have you:

- Considered how fertility may be affected by treatment
- Discussed fertility preservation options with your care team

Your future matters, including your family-building goals. Through the Genetix Patient Support Program, you can get access to information about fertility preservation options to help you plan ahead.

Putting Your Plan Into Action

Planning for treatment means thinking about more than just the medical steps. Because LYFGENIA can be given only at a specialized treatment center, you'll need to consider travel, time away, costs, and day-to-day logistics. Have you:

- Talked with your hematologist about taking the next step with LYFGENIA gene therapy
- Located a Qualified Treatment Center (QTC) near you
[Find one at www.lyfgenia.com/find-a-qualified-treatment-center]
- Considered travel and spending time away from home if you don't have a QTC nearby
- Made a plan for transportation before and during treatment, as well as after recovery
- Thought about financial considerations and insurance
- Enrolled in the Genetix Patient Support Program for support along the way



If you're thinking about cost, you're not alone. It's important to know that the price you may have seen isn't what most people pay out of pocket. Your care team and the **Genetix Patient Support Program** can help you understand your coverage and financial support options.

Find a Qualified Treatment Center



Important Safety Information (cont'd)

What is the most important safety information I should know about LYFGENIA? (cont'd)

Monitoring will include blood tests that measure your blood cell counts and evaluation of the blood cells where the gene product is present with specialized tests. If these tests are abnormal, additional testing may be recommended by your doctor, which might include more frequent blood tests and a bone marrow evaluation.

You should talk to your doctor about the benefits and risks of LYFGENIA, and about your treatment options. Your doctor may evaluate if you have risk factors that increase your chances of developing blood cancer after LYFGENIA. Blood cancer may cause no symptoms, or symptoms can be general.

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You should talk to your doctor about the benefits and risks of LYFGENIA, and about your treatment options. Your doctor may evaluate if you have risk factors that increase your chances of developing blood cancer after LYFGENIA. Blood cancer may cause no symptoms, or symptoms can be general. You or your caregiver should call your healthcare provider right away for any of these signs or symptoms:

- Abnormal bruising or bleeding (including nosebleed)
- Blood in urine, stool, or vomit
- Coughing up blood
- Severe headache
- Unusual stomach or back pain
- Fever (100.4°F/38°C or higher)
- Swollen glands
- Abnormal tiredness

If you are diagnosed with a cancer, have your treating physician contact Genetix Biotherapeutics at 1-833-999-6378.

You may experience side effects associated with other medicines, including a chemotherapy medicine, administered as part of the LYFGENIA treatment regimen. After receiving the chemotherapy, it may not be possible for you to become pregnant or father a child. You should consider discussing options for fertility preservation with your doctor before treatment. Talk to your healthcare provider about the risks and benefits of all medicines involved in your treatment. It is important that you or your caregiver tell your healthcare providers that you have received LYFGENIA.

How will I get LYFGENIA?

STEP 1: LYFGENIA is made specifically for you from your own blood stem cells. Your healthcare provider will collect your blood stem cells through a procedure/process called mobilization and apheresis. This process takes approximately one week and may need to be repeated to obtain a sufficient number of cells.

‘Back-up’ stem cells (or ‘rescue cells’) are also collected and stored at the treatment center. This is a precaution in case there is a problem in the treatment process. If this happens, your back-up stem cells will be given back to you. If you receive back-up cells, you will have no benefit from LYFGENIA.

Important Safety Information (cont’d)

STEP 2: Your blood stem cells will be sent to a manufacturing site where they are used to make your LYFGENIA. It typically takes 10 to 15 weeks from the time your cells are collected to make and test LYFGENIA before it is shipped to your healthcare provider, but the time may vary and be up to 22 weeks.

STEP 3: Before you receive LYFGENIA, your healthcare provider will give you chemotherapy for a few days to make room in the bone marrow. You will be admitted to the treatment center for this step and remain there until after LYFGENIA infusion.

STEP 4: LYFGENIA is given by an intravenous infusion. You may receive more than one bag of LYFGENIA. Each bag is infused in 30 minutes or less.

After LYFGENIA infusion, you will stay in the treatment center for approximately 3-6 weeks so that your healthcare team can closely monitor your recovery. Your healthcare provider will determine when you can go home.

What should I avoid after receiving LYFGENIA?

- Do not donate blood, organs, tissues or cells.

What are the possible side effects of LYFGENIA?

The possible side effects of LYFGENIA on the day of treatment include: Low blood pressure and hot flush.

The possible side effects of LYFGENIA following treatment include: **Blood cancer** and longer time for platelets to recover, which may reduce the ability of blood to clot and may cause bleeding.

These are not all the possible side effects of LYFGENIA. Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

General Information

It is important that you have regular check-ups with your healthcare provider to detect any adverse effects and to confirm that LYFGENIA is still working. Talk to your healthcare provider about any concerns.

Patients treated with LYFGENIA are encouraged to enroll in a post-marketing study to assess the long-term safety of LYFGENIA and the risk of blood cancers occurring after treatment with LYFGENIA. Patients should discuss the option to participate with their physician.

LYFGENIA uses a vector that is based on the blueprint of the human immunodeficiency virus (HIV) to deliver genetic material to your cells. LYFGENIA will not give you a HIV infection. Treatment with LYFGENIA may cause a false-positive HIV test result by some commercial tests (specifically, a PCR-based test). If you need to have an HIV test, talk with your healthcare provider about the appropriate test to use.

Please see [full Prescribing Information](#), including **Boxed WARNING** and **Medication Guide for LYFGENIA**.



Genetix Patient Support Program: Dedicated Support for *Your Journey* With LYFGENIA

From the moment you decide you want to explore treatment with LYFGENIA, the **Genetix Patient Support Program** is available to you.

Once enrolled, you will be connected at no cost with a dedicated Patient Navigator who can:

- Offer ongoing support navigating the journey before, during, and after treatment
- Connect you with a QTC and assist with travel and lodging*
- Guide you through insurance and financial assistance options*
- Provide resources and support for fertility preservation*
- Offer peer-to-peer support by linking you to others who've experienced treatment firsthand

To connect with a Patient Navigator:



Call

1-833-888-6378



Email

patientsupport@genetixbiotx.com



Visit

GenetixPatientSupport.com

*Eligibility requirements and restrictions apply. Patient must be enrolled in Patient Support Services to determine eligibility for, and participate in, program offerings.

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