

Someday, life with sickle cell disease could be different.
Someday, I could be my own change, my own donor.

Someday
is today

Actor portrayals throughout.

LYFGENIA™ is the longest-studied* approved gene therapy for sickle cell disease

*The primary clinical trial that evaluated LYFGENIA started in February 2015.

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. Sickle cell disease is a genetic, inherited, lifelong disease caused by an alteration in one of the genes in the red blood cell, the beta-globin gene, that causes the normal disc-shaped red cells to take the shape of a sickle, causing anemia and vaso-occlusive events, like a pain crisis. 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 information I should know about LYFGENIA?

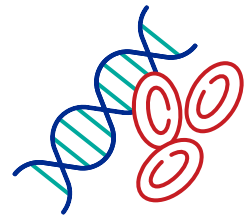
Patients treated with LYFGENIA have developed blood cancers. Treatment with LYFGENIA may increase your risk of developing blood cancer. Blood cancer can develop many years after treatment with LYFGENIA. Blood cancer can be life-threatening and/or cause death.

Please see [Important Safety Information](#) on [pages 16-17](#) and [full Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#) for LYFGENIA.


lyfgenia™
(lovotibeglogene autotemcel)
suspension for IV infusion

Learn about LYFGENIA, a *gene therapy option*

Managing sickle cell disease can be challenging and affect different aspects of your life. What if you had the ability to treat sickle cell disease from within, without a donor?



LYFGENIA is a one-time treatment that adds functional copies of the beta-globin gene to your blood stem cells to help your body make anti-sickling hemoglobin, so that you can potentially decrease or stop experiencing vaso-occlusive events (VOEs).

LYFGENIA is for individuals 12 years or older with a history of vaso-occlusive events (VOEs).

This resource is not intended to make a diagnosis or treatment recommendation or provide medical advice. You should discuss any questions with your healthcare team.

Important Safety Information (cont'd)

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

Because of the risk of blood cancer, 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.

Because of the risk of cancer, it is important for you to be monitored at least every 6 months for a minimum of 15 years after LYFGENIA. 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, which can tell your doctor if a blood cancer is developing.

LYFGENIA is specifically made for you
using *your own cells*

Please see [Important Safety Information](#) on pages 16-17 and full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#) for LYFGENIA.

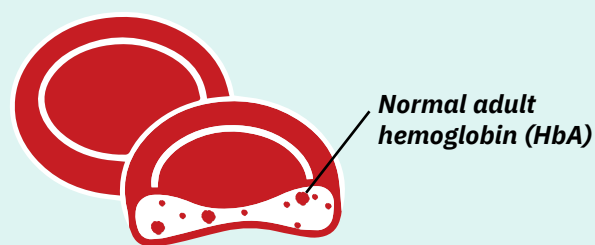
2 Words that are underlined indicate terms you can find in the Glossary, on pages 28-29.



What is LYFGENIA?
Why LYFGENIA?
Steps of treatment
Support
Talk to your doctor

Sickle cell is a *lifelong genetic disease* marked by unpredictable, progressive symptoms

Knowing the cause—a gene mutation that produces abnormal hemoglobin—is an important first step in making decisions with your doctor on how to treat it.



Normal red blood cell



Sickled red blood cell

- A change in both copies of the *HBB* gene causes red blood cells to make an abnormal form of hemoglobin (the protein in red blood cells that carries oxygen) called sickle hemoglobin (HbS) instead of adult hemoglobin (HbA)
- Repeated blockages and damage to blood vessels over time can prevent your organs and tissue from getting the oxygen they need, causing vaso-occlusive events (VOEs)



Current disease-modifying therapies do not address the disease at the genetic level

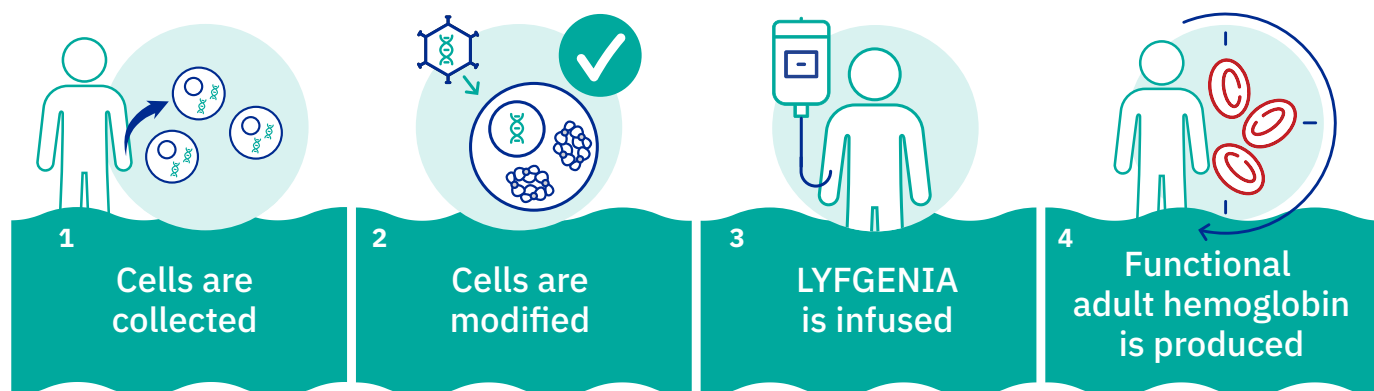
While current treatment options such as disease-modifying therapies (DMTs), oral and IV pain medications, and blood transfusions are designed to help manage sudden and severe symptoms, they require lifelong use.

Allogeneic stem cell transplants (also called bone marrow transplants or stem cell transplants) are one-time treatments, but are usually recommended for people with sickle cell disease under the age of 16 with a sibling donor who is a match and is available. Allogeneic stem cell transplants may also carry risks of donor-related complications such as graft-versus-host disease.

Learn about an option that addresses sickle cell disease at the *genetic level*

How LYFGENIA works at the *genetic level*

LYFGENIA is a gene addition therapy designed to add genetic material to your cells



1. Blood stem cells are collected.
2. LYFGENIA is created by adding working copies of the *HBB* (beta-globin) gene to your collected cells through a viral vector.
3. Your modified cells (LYFGENIA) are returned to your body through an infusion.
4. Your modified cells go through a process called engraftment, which leads to the production of new red blood cells containing functional adult hemoglobin.

Important Safety Information (cont'd)

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

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

LYFGENIA *helps your body* produce functional adult hemoglobin to potentially decrease or stop vaso-occlusive events (VOEs)

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Vectors deliver genetic material to your cells

It's important to understand how vectors work and also know what they don't do.

LYFGENIA uses a type of vector known as a lentiviral vector (LVV). Below is information that is helpful to discuss with your doctor before deciding on treatment.

What is a vector?

A vector is a vehicle designed to deliver genetic material directly to your cells.

What types of vectors are there?

There are viral and non-viral vectors.

Why are viral vectors used?

Viruses are very efficient at delivering genetic material to cells of the body.

Though vectors are based on viruses, they do not contain any of the parts of the virus that can cause an infection. They act as a delivery system for genetic materials into cells.

What type of vector does LYFGENIA use?

LYFGENIA uses the most widely studied viral vector type: a lentiviral vector. The most well-studied lentivirus is human immunodeficiency virus (HIV), and scientists have used its blueprint to design lentiviral vectors, which include some but not all parts of the virus.

How long have lentiviral vectors been studied?

Lentiviral vectors have been studied for the last 20 years.

Can you get HIV from LYFGENIA?

No. LYFGENIA cannot cause HIV infection because parts of the HIV virus responsible for causing the infection have been removed.

LYFGENIA may cause a false-positive HIV test result if using a PCR-based test. If you need to have an HIV test, talk with your doctor about which test to use.

Talk to your doctor about viral vectors, how they work, and their importance in LYFGENIA

Important Safety Information (cont'd)

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

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

You may experience side effects associated with other medicines administered as part of the LYFGENIA treatment regimen. Talk to your physician regarding those possible side effects. Your healthcare providers may give you other medicines to treat your side effects. It is important that you or your caregiver tell your healthcare providers that you have received LYFGENIA.

What should I avoid after receiving LYFGENIA?

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

Important Safety Information (cont'd)

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

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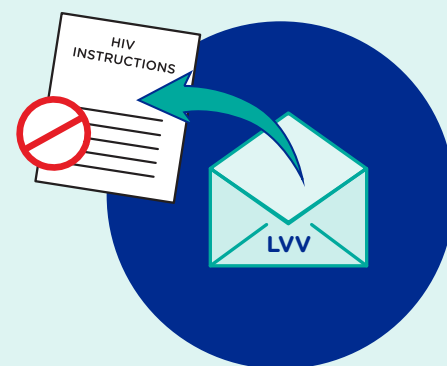
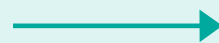
Let's learn more about *lentiviral vectors*

LYFGENIA uses a type of vector called a lentiviral vector (LVV). To help understand how lentiviral vectors work to deliver genetic material to your stem cells, imagine the vector as an “envelope” containing genetic material (a “letter”) and your stem cells as the “address” waiting to receive the letter. Using a lentiviral vector allows the genetic materials to reach your stem cells, like a letter reaching an address.

While LYFGENIA will not cause HIV infection, it may cause a false-positive HIV test result if using a PCR-based test. If you need to have an HIV test, talk with your doctor about which test to use.



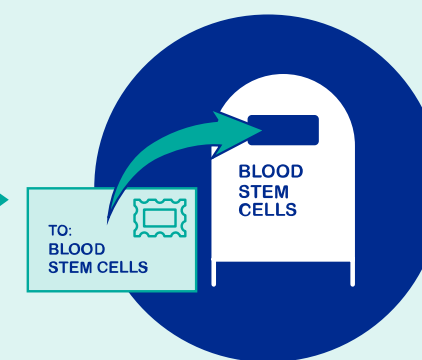
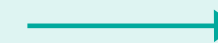
A vector is like an envelope used to deliver genetic materials directly to your stem cells



The lentiviral vector does NOT include parts of the virus that cause HIV infection and is built only using the parts of HIV that are good at delivering genetic material to your stem cells



Working copies of the *HBB* (beta-globin) gene are added to the lentiviral vector



The lentiviral vector then delivers the working copies of the *HBB* (beta-globin) gene directly into your stem cells

Important Safety Information (cont'd)

General Information

It is important that you have regular check-ups with your healthcare provider, including blood tests at least every 6 months as advised by 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.

Important Safety Information (cont'd)

General Information (cont'd)

LYFGENIA will not give you a human immunodeficiency virus (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.

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LYFGENIA is the longest-studied* *approved* gene therapy for sickle cell disease

The safety of LYFGENIA was studied in individuals with sickle cell disease in 1 clinical trial and 1 long-term follow-up study.



The clinical trial included

54 people

who initiated stem cell collection†



Individuals with a median age of

25 years

(minimum age 12 years, maximum age 43 years)



Median duration of follow-up for individuals treated with LYFGENIA‡:

42 months

(minimum of 12 months, maximum of 87 months)

*The primary clinical trial that evaluated LYFGENIA started in February 2015.
†45 people were treated with LYFGENIA.

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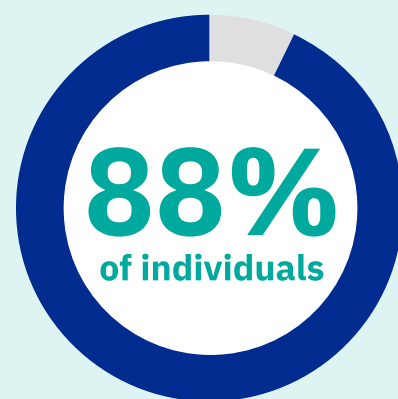
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A one-time transformational therapy with the potential to decrease or stop VOs

The efficacy of LYFGENIA was studied in 36 individuals. 32 individuals were evaluated for the number of vaso-occlusive events (VOEs) they experienced **between 6-18 months after treatment**:



did not experience any vaso-occlusive events (VOEs)
(28/32 people)



did not experience any severe vaso-occlusive events (sVOEs)
(30/32 people)

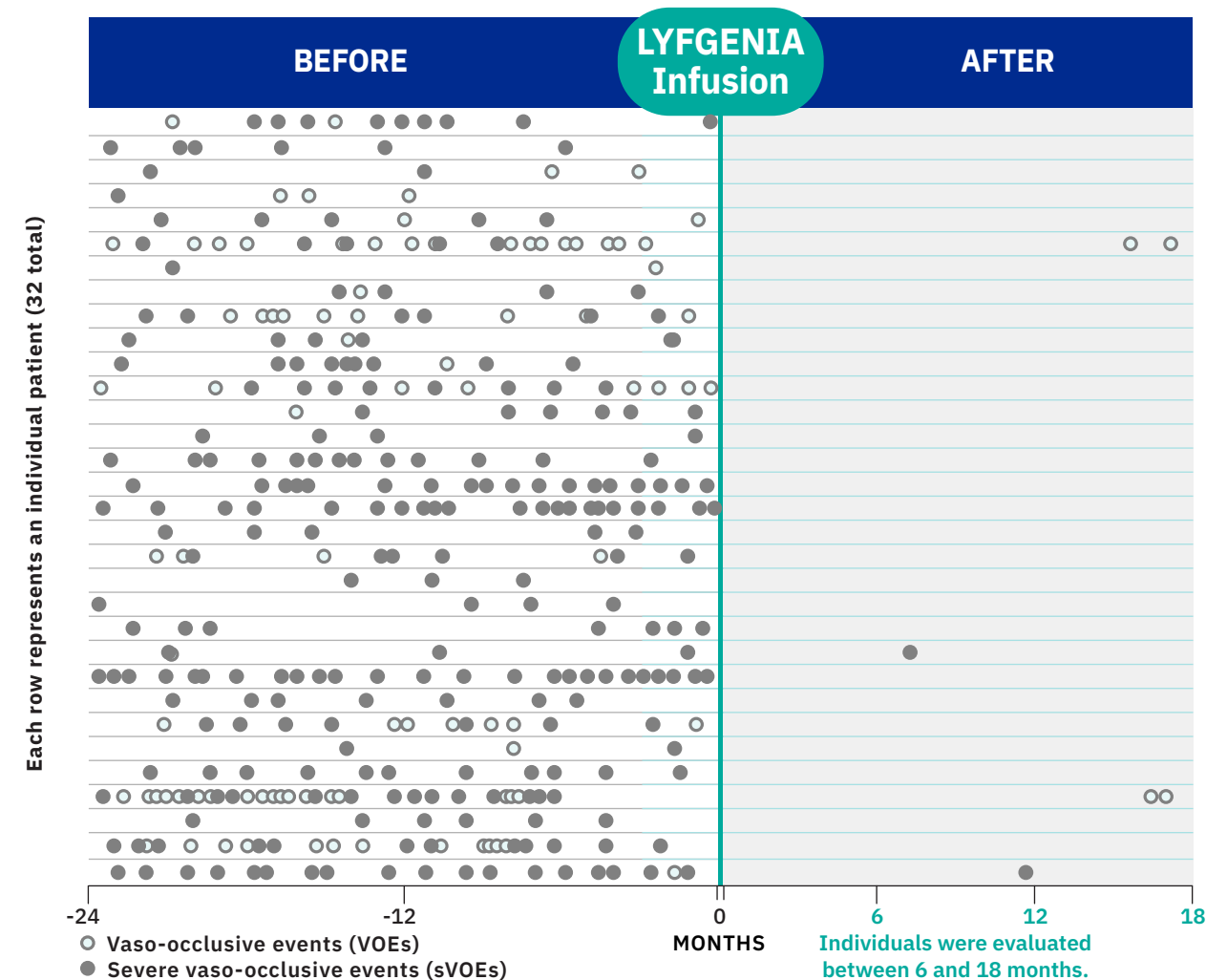
- Four individuals who did not experience any vaso-occlusive events (VOEs) between 6-18 months after treatment later experienced vaso-occlusive events (VOEs)
- No clinically meaningful differences in efficacy or safety were observed between adults and adolescents
- The median duration of follow-up for efficacy for the 36 individuals who received LYFGENIA was 38 months (minimum of 12 months; maximum of 61 months)
- Five individuals with a history of stroke or vasculopathy were treated. They were at least 18 years old and on chronic transfusion therapy prior to LYFGENIA infusion. At 44-60 months' follow-up, all 5 individuals remain transfusion independent without repeated stroke

Important Safety Information (cont'd)

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

Because of the risk of cancer, it is important for you to be monitored at least every 6 months for a minimum of 15 years after LYFGENIA. 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.

VASO-OCCLUSIVE EVENTS (VOEs) BEFORE AND AFTER LYFGENIA INFUSION



sVOEs were also counted as VOEs.

This figure is not included in the LYFGENIA Prescribing Information.

- **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
- **Severe vaso-occlusive events (sVOEs)** were defined as either of the following events: vaso-occlusive events (VOEs) requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving IV medications at each visit, or priapism requiring any level of medical attention

Important Safety Information (cont'd)

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

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, which can tell your doctor if a blood cancer is developing.

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Important Safety Information



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

Patients treated with LYFGENIA have developed blood cancers. Treatment with LYFGENIA may increase your risk of developing blood cancer. Blood cancer can develop many years after treatment with LYFGENIA. Blood cancer can be life-threatening and/or cause death. Because of the risk of blood cancer, 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.

Because of the risk of cancer, it is important for you to be monitored at least every 6 months for a minimum of 15 years after LYFGENIA. 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, which can tell your doctor if a blood cancer is developing.

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 bluebird bio at 1-833-999-6378.

You may experience side effects associated with other medicines administered as part of the LYFGENIA treatment regimen. Talk to your physician regarding those possible side effects. Your healthcare providers may give you other medicines to treat your side effects. It is important that you or your caregiver tell your healthcare providers that you have received LYFGENIA.



How will I get LYFGENIA?

Before treatment: Your healthcare providers will give you other medicines, including a chemotherapy medicine, as part of your treatment with LYFGENIA. It's important to talk to your healthcare provider about the risks and benefits of all medicines involved in your treatment. You will be admitted to a treatment center during this process (see Step 3).

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.

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.

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 negative 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, including blood tests at least every 6 months as advised by 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 will not give you a human immunodeficiency virus (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.

LYFGENIA—a *path* to consider taking

Where will you receive LYFGENIA?



Before treatment, individuals and their healthcare providers will work together to consider whether LYFGENIA is right for them.

People who are prescribed LYFGENIA will receive treatment as a 1-time infusion at a Qualified Treatment Center (QTC). Each QTC has been carefully selected based on their expertise in areas such as transplants or cell and gene therapy.

It's important to consult with your regular physicians as well as specialists in gene therapy.

We want you to have the support you need



A **my bluebird support** Patient Navigator can help answer additional questions about the treatment process, navigating insurance, and identifying Qualified Treatment Center options.

Visit mybluebirdsupport.com and page 24 for more information.

Important Safety Information (cont'd)

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

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)
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- Fever (100.4°F/38°C or higher)
- Swollen glands
- Abnormal tiredness

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

A process focused on *you*

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One-time *treatment process*

Treatment with LYFGENIA involves coordinating with a care team and confirming that gene therapy is an appropriate choice for you and your family. Planning is a large part of this stage, from healthcare coverage and impacts on daily life (including work and family responsibilities) to chemotherapy and fertility discussions.

6 key steps

It's important to keep in mind that the time frames are meant as an approximate guideline. Your journey may look different depending on your circumstances, unique to you and your care team at the Qualified Treatment Center (QTC).



Step 1:
Pre-treatment



Step 2*:
Stem Cell Collection



Step 3:
LYFGENIA Creation



Step 4:
Conditioning Chemotherapy



Step 5:
LYFGENIA Infusion



Step 6:
Recovery and Long-Term Follow-Up

Additional safety considerations

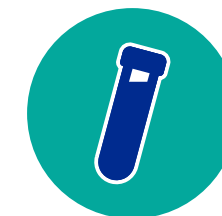
LYFGENIA is made from patients' own cells; therefore, there have been no cases of graft failure or graft rejection.

*This step may need to be repeated.



Step 1: Pre-treatment

- Part of pre-treatment is understanding that you will receive other medicines, including chemotherapy, during the LYFGENIA treatment process. It's important to talk to your healthcare provider about the risks and benefits of all medicines involved in your treatment
- Before stem cell collection, you'll be required to undergo blood transfusions for at least 2 cycles (one per month). This is done to maintain the proper hemoglobin levels needed for stem cell collection



Step 2*: Stem Cell Collection

(~1 week at a QTC)

- Your doctor will collect your blood stem cells through mobilization (moving stem cells from your bone marrow into the blood) and apheresis (withdrawing blood to separate the plasma and blood stem cells needed to create LYFGENIA)
- “Back-up” stem cells (or “rescue cells”) are also collected and stored at the hospital. 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
- In clinical studies, most people treated with LYFGENIA provided the minimum number of blood stem cells to manufacture LYFGENIA with 1 or 2 cycles of mobilization and apheresis, but **additional cycles may be required**

Important Safety Information (cont'd)

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

You may experience side effects associated with other medicines administered as part of the LYFGENIA treatment regimen. Talk to your physician regarding those possible side effects. Your healthcare providers may give you other medicines to treat your side effects. It is important that you or your caregiver tell your healthcare providers that you have received LYFGENIA.

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One-time *treatment process* (continued)



Step 3:

LYFGENIA Creation

(10-15 weeks)

Your healthcare team will send your cells to a manufacturing site to create 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 4:

Conditioning Chemotherapy

(4 days plus ≥ 2 days of recovery at a QTC)

Before you receive LYFGENIA, you'll be admitted to the QTC to undergo a 4-day course of conditioning with chemotherapy to make room in your bone marrow for LYFGENIA. You'll remain in the QTC until after LYFGENIA infusion

- After receiving 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



Step 5:

LYFGENIA Infusion

(~30 minutes per bag at a QTC)

After conditioning, the specialized healthcare team at the QTC will administer LYFGENIA through an IV infusion. You may receive anywhere from 1 to 4 bags of LYFGENIA. The number of bags varies per person



Step 6:

Recovery and Long-Term Follow-Up

(~3-6 weeks of monitoring at a QTC followed by long-term follow-up for at least 15 years)

Following your treatment with LYFGENIA, you'll remain at the QTC for approximately 3-6 weeks of careful monitoring until release by your treating physician

- Following your treatment with LYFGENIA, make sure to work with your QTC team, along with your regular healthcare professional, to establish a long-term follow-up plan and monitoring. The QTC may require you to return for follow-up care at their center. It is important that you have regular checkups with your healthcare professional to detect any adverse effects and to confirm that LYFGENIA is working*
- Because of the risk of cancer, it is important for you to be monitored at least every 6 months for a minimum of 15 years after LYFGENIA. Monitoring will include blood tests. If these tests are abnormal, additional testing may be recommended, which can include more frequent blood tests and a bone marrow evaluation. If you are diagnosed with a cancer, have your treating physician contact bluebird bio at **1-833-999-6378**

*You'll also be encouraged to enroll in the LYFGENIA registry by calling bluebird bio at 1-833-999-6378, which collects long-term data on the safety and effectiveness of treatment for 15 years. Your participation in the registry is voluntary.

Important Safety Information (cont'd)

What should I avoid after receiving LYFGENIA?

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

What are the possible side effects of LYFGENIA?

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What are the possible side effects of LYFGENIA? (cont'd)

These are not all the possible side effects of LYFGENIA. Call your doctor for medical advice about side effects. 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.

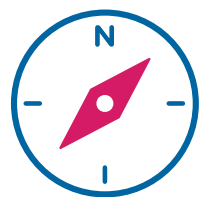
Please see **Important Safety Information on pages 16-17** and full **Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.**

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Support starts today

Rely on **my bluebird support** along the way

Your Patient Navigator will be available to help navigate, educate, and elevate when needed during the decision-making process with your doctor and throughout the treatment process.



Navigate

Guiding you and your loved ones through the treatment journey while connecting you with helpful people and organizations



Educate

Sharing important resources about gene therapy and the benefits information you need to access treatment with insurance



Elevate

Collaborating with you to help reach your personal health goals



For additional support and to connect with a Patient Navigator:

call 1-833-888-NEST (6378)

email mybluebirdsupport@bluebirdbio.com

visit mybluebirdsupport.com

my bluebird support: A dedicated copilot
for *your journey* with **LYFGENIA**

Please see **Important Safety Information** on pages 16-17 and full **Prescribing Information**, including **Boxed WARNING** and **Medication Guide** for LYFGENIA.

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Questions for Your Doctor

Deciding to move forward with LYFGENIA is a big decision. Before discussing LYFGENIA with your doctor (or your loved one's doctor), consider the following questions to help you get started.

Thinking about LYFGENIA

Am I a candidate for LYFGENIA?

How do you think LYFGENIA could change my experience with sickle cell disease?

What safety considerations should I know about LYFGENIA?

What are the possible side effects of LYFGENIA?

What should I do if I'm planning on having kids?

Moving forward with LYFGENIA treatment

Where will I go to receive LYFGENIA?

Who will oversee my treatment?

What can I expect at the Qualified Treatment Center (QTC)?

Where will I be monitored after LYFGENIA, and for how long?

Questions for Your QTC Care Team

The following questions can help you get a better understanding of the treatment process in general during consultations with your healthcare team.

Is there anything I should avoid after treatment with LYFGENIA?

Who will monitor my follow-up?

What are the most important things to know about receiving treatment at a QTC?

What will I need to consider and plan for in order to move forward with LYFGENIA (eg, transportation, cost, or community and family support)? What logistics will I need to address beforehand?

What do I need to know about what happens after treatment with LYFGENIA? What does follow-up care look like?

What should I do if I experience any sickle cell disease-related symptoms during or after treatment?

What should I do if I experience side effects during or after treatment?

What else should I know about LYFGENIA before I start planning for treatment?

Please see [Important Safety Information](#) on pages 16-17 and full [Prescribing Information](#), including [Boxed WARNING](#) and [Medication Guide](#) for LYFGENIA.


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Important terms you should know

Reference this page to revisit any new or unfamiliar terms in this brochure, to help your understanding as you manage sickle cell disease care.

Allogeneic stem cell transplant: replacing blood stem cells with those from a donor match; usually recommended in people under age 16 with sickle cell disease. Also known as a hematopoietic stem cell transplant, or HSCT or bone marrow transplant (BMT)

Apheresis: part of the stem cell collection process that involves separating blood stem cells from blood cells using a machine

Blood stem cell: an immature cell that has the potential to develop into any blood cell type, including white blood cells, red blood cells, and platelets

Conditioning: the process of making room in your bone marrow for gene therapy or a stem cell transplant through chemotherapy. Conditioning is required for all transplant options—whether it's gene therapy or a donor stem cell transplant

Engraftment: the process by which transplanted stem cells travel through the blood to the bone marrow, where they begin to make new white blood cells, red blood cells, and platelets

Gene: a sequence of DNA responsible for controlling inherited traits

Gene addition therapy: a treatment approach that uses a viral vector to add genes to give cells a new set of instructions, with the goal of changing the course of the disease

Graft-versus-host disease: a risk of donor stem cell transplant where the donated stem cells attack the host's body due to viewing it as foreign

Hemoglobin: a protein in your red blood cells that carries oxygen throughout your body

Infusion: the process by which LYFGENIA is administered into your veins

Lentiviral vector: a type of vector. The most well-studied lentivirus is HIV, and scientists have used its blueprint to design lentiviral vectors. Though vectors are based on viruses, they do not contain any parts of the virus that can cause an HIV infection

Median: the middle number that separates the higher half from the lower half in a range of numbers

Mobilization: the first part of the stem cell collection process, moving stem cells out of the bone marrow and into the circulating blood

Mutation: an abnormal change in a gene that causes it to malfunction

my bluebird support: a program to help guide you through each step of the LYFGENIA treatment journey

Patient Navigator: a patient support specialist at [my bluebird support](#) who is knowledgeable about LYFGENIA and is equipped with resources to help navigate questions, including concerns about healthcare insurance or treatment planning

Proteins: the molecules within cells that are responsible for performing important functions, such as delivering oxygen throughout the body

Qualified Treatment Center (QTC): a hospital that has been carefully selected based on expertise in areas such as transplants or cell and gene therapy, with staff trained to administer LYFGENIA

Red blood cell: a hemoglobin-containing cell that carries oxygen throughout your body

Severe vaso-occlusive events (sVOEs): in a LYFGENIA clinical study, sVOEs were defined as vaso-occlusive events (VOEs) requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving IV medications at each visit, or priapism requiring any level of medical attention

Sickle hemoglobin: an abnormal form of the hemoglobin protein including red blood cells that are sickled (or half-moon shaped)

Vaso-occlusive events (VOEs): in a LYFGENIA clinical study, 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

Vector: a delivery system used to introduce genetic material into the cell

Important Safety Information (cont'd)

General Information

It is important that you have regular check-ups with your healthcare provider, including blood tests at least every 6 months as advised by your healthcare provider, to detect any adverse effects and to confirm that LYFGENIA is still working. Talk to your healthcare provider about any concerns.

Important Safety Information (cont'd)

General Information (cont'd)

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.

Please see [Important Safety Information on pages 16-17](#) and full [Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA](#).


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Someday, you could see life with sickle cell disease differently.

Why wait for someday?

Ask your doctor about LYFGENIA today.
Visit LYFGENIA.com to learn more.

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. Sickle cell disease is a genetic, inherited, lifelong disease caused by an alteration in one of the genes in the red blood cell, the beta-globin gene, that causes the normal disc-shaped red cells to take the shape of a sickle, causing anemia and vaso-occlusive events, like a pain crisis. 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 information I should know about LYFGENIA?

Patients treated with LYFGENIA have developed blood cancers. Treatment with LYFGENIA may increase your risk of developing blood cancer. Blood cancer can develop many years after treatment with LYFGENIA. Blood cancer can be life-threatening and/or cause death. Because of the risk of blood cancer, 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.

Please see [Important Safety Information on pages 16-17](#) and full [Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA](#).


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