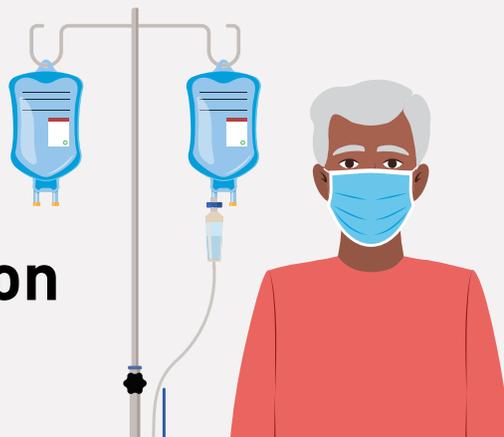


What to expect during a COVID-19 neutralizing antibody treatment infusion



If you've recently been diagnosed with the COVID-19 virus, your doctor may offer you a new drug called **bamlanivimab** (bam-la-NIV-i-mab).

The research so far shows that for certain people, taking this drug may help limit the amount of virus in the body. This may help their symptoms improve sooner — and they may be less likely to need to go to the hospital.^{1,2} But bamlanivimab is a new drug that's still being studied, so there's a lot that scientists don't know about the benefits and risks.

In this easy-to-read guide, you'll learn about this new drug and what to expect before, during, and after treatment.

Important facts about bamlanivimab¹:

Bamlanivimab is investigational, which means it's still being studied. Bamlanivimab has not been approved, but has been authorized for emergency use by the United States Food and Drug Administration (FDA), to treat mild to moderate symptoms of COVID-19 in non-hospitalized adults and adolescents (12 years of age and older weighing at least 88 pounds (40 kg)) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization.

FDA has authorized bamlanivimab for emergency use only during the COVID-19 pandemic.

Bamlanivimab is authorized for the treatment of mild to moderate symptoms of COVID-19 in non-hospitalized adults and adolescents (12 years of age and older weighing at least 88 pounds (40 kg)) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of bamlanivimab under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

This guide is not a substitute for the official fact sheet. For information on the authorized use of bamlanivimab and mandatory requirements under the Emergency Use Authorization, please review the [FDA Letter of Authorization](#), [Fact Sheet for Healthcare Providers](#), and [Fact Sheet for Patients, Parents and Caregivers](#).

Who is this drug for?

Bamlanivimab is a treatment option for people with COVID-19 who:¹

- Have positive results of direct SARS-CoV-2 viral testing
- Are age 12 or older
- Have had mild to moderate symptoms for 10 days or less
- Are at high risk to get very sick from COVID-19

This drug is **not** for people who are already in the hospital because of their COVID-19 symptoms.

Am I at high risk?

For adults, bamlanivimab may be an option if you meet at least one of the following criteria:

- Are age 65 or older
- Have obesity, with a body mass index (BMI) of 35 or higher
- Have diabetes, chronic kidney disease, or a condition that weakens the immune system
- Take medication that weakens the immune system
- Are age 55 or older and have at least one of the following:
 - Heart disease
 - High blood pressure
 - A long-term lung disease

If you're not sure whether bamlanivimab could be an option for you, talk with your doctor. For more detailed information about risk, see the [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents and Caregivers](#) at bamlanivimab.com.



What is COVID-19?

COVID-19 is a disease caused by a type of virus called a coronavirus. Common symptoms include fever, cough, and having trouble breathing.

Some people with COVID-19 have many symptoms, and some have few or no symptoms. And though most people get better within 2 weeks, some people are very sick for a long time — or even die.

There's no way to know for sure who will get very sick with COVID-19, but some people are at higher risk, including older adults and people with certain health conditions.³

For adolescents (12 years of age and older weighing at least 88 pounds [40 kg]), bamlanivimab may be an option if the child meets at least one of the following criteria:

- Has obesity, with a body mass index (BMI) equal to or greater than 85 percent of children the same age or gender⁴
- Has heart disease
- Has sickle cell disease
- Has a developmental condition, like cerebral palsy
- Has asthma or a long-term lung disease that requires daily medication for control
- Regularly uses medical technology, like a ventilator or feeding tube

What are the side effects?

Side effects can range from mild to serious and may include:¹

- Fever, chills, or sweating
- Nausea (upset stomach)
- Headache, muscle aches, or chest discomfort or pain
- Wheezing or shortness of breath (trouble breathing)
- Dizziness, low or high blood pressure, or fast or slow heartbeat
- Itching, rash, hives, or swollen lips, face, or throat
- Feeling weak, confused, or tired

Tell your doctor or nurse right away if you have any side effects, or your symptoms get worse, during or after your infusion. Some of these side effects may be signs of a serious allergic reaction. Keep in mind that only a limited number of people have taken bamlanivimab, and scientists are still learning about its side effects and risks. Serious and unexpected side effects may happen.

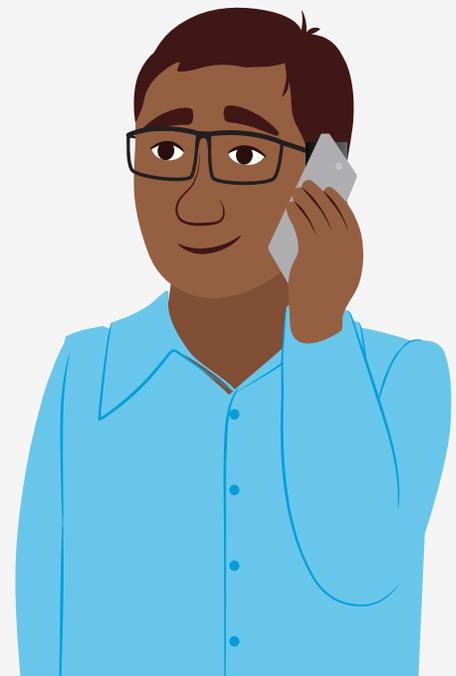
It's also possible that bamlanivimab could make it harder for your body to fight off a future COVID-19 infection — and it could make a future COVID-19 vaccine less effective for you. Scientists haven't done specific studies to address these possible risks.¹ If you have any questions, talk with your doctor.

What if I'm pregnant or breastfeeding?

Scientists haven't treated many pregnant or breastfeeding people with bamlanivimab. It's possible that the drug may have more benefits than risks for them and their babies.¹ Talk to your doctor about your options and your specific situation.

Before you take bamlanivimab, tell your healthcare provider if you:

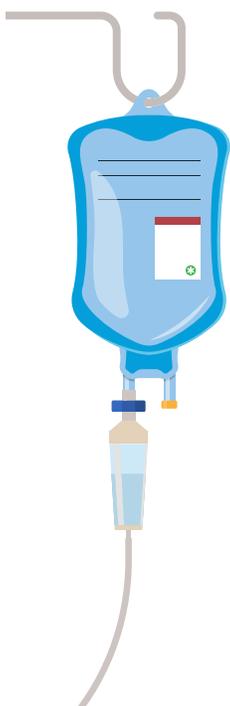
- Have any allergies, diseases, or health conditions
- Are pregnant or plan to get pregnant
- Are breastfeeding or plan to start breastfeeding
- Are taking any medicines, including prescription drugs, over-the-counter drugs, vitamins, or herbal products.



How does the drug work?

When there's a virus in your body, like COVID-19, your immune system makes **antibodies** to fight it off. But it takes time for your body to make antibodies for a new virus — and in the meantime, you could get very sick.

Bamlanivimab is a **neutralizing antibody drug**. That means it contains man-made antibodies that are similar to the antibodies of patients who recovered from COVID-19. Scientists think that these antibodies may help limit the amount of COVID-19 virus in your body. This could give your body more time to learn how to make its own antibodies.⁵



How will I take the drug?

You only need to take the drug **1 time**. It's usually given at a hospital, clinic, or infusion center, and the appointment takes about 2 hours, but times may vary.

The treatment is an **intravenous (IV) infusion**, meaning the drug goes directly into your blood over about 16 to 60 minutes. A nurse will insert a small needle into a vein in your arm to give you the drug.¹

Is this drug safe?

Scientists aren't sure yet. They're still studying the drug in clinical trials, and there's a lot they don't know about the benefits and risks.

Because of the COVID-19 pandemic, the FDA has given a temporary Emergency Use Authorization for doctors to use bamlanivimab with certain patients.¹

This means that based on the results of the research so far, the FDA has found that the drug may have more benefits than risks in treating COVID-19 during the pandemic.



Does the infusion hurt?

With any infusion treatment, you may feel a pinch or sting when the needle first goes in, but the feeling often goes away after a few seconds.⁷ If you feel any pain during the infusion, tell the nurse right away.

After the infusion, some people may have pain, bleeding, bruising, soreness, or swelling in the place where the needle went in. In some cases, this may lead to more serious problems, like an infection.¹

If you're not sure whether what you're feeling after the infusion is normal, it's always okay to call your doctor or the infusion center and check.

How can I get ready for my appointment?

Plan for the infusion appointment to take about 2 hours but times may vary. Most people are able to go home the same day, unless they have very serious side effects from the infusion.^{1,6}

Before your appointment, make sure to get a good night's sleep, drink plenty of water, and eat a light meal. Wear warm, comfortable clothes, including a shirt with sleeves you can roll up over your elbows. It's also important to wear a mask to help prevent the spread of COVID-19.^{8,9}

Ask the clinic staff if there's anything else you need to know. They may ask patients with COVID-19 to take some extra steps to help keep the virus from spreading. You may want to ask questions like:

- What do I need to bring with me?
- When I arrive, should I call instead of coming into the waiting room?
- Will I need someone to give me a ride home after the infusion?

To help prevent the spread of COVID-19, friends and family usually can't be with you during the infusion. If you have any concerns about this, talk with the clinic staff before your appointment.¹⁰



Is this drug the same as a vaccine?

No. Vaccines help your body make its own antibodies over time. Antibody drugs give you antibodies that may start working more quickly to help your body fight a virus.¹¹

Bamlanivimab is not a vaccine. It does not have any COVID-19 virus in it.

What is it like to get the infusion?

Starting the infusion

When you get to the hospital, clinic, or infusion center, a nurse will show you to a chair where you can sit comfortably during the infusion process. The nurse will clean your arm with a special liquid that kills germs. Then they'll insert a small needle into a vein and start the flow of medicine.

During the infusion

Once the infusion has started, it takes about 1 hour. From time to time, a nurse will come to check on you and measure your temperature, breathing, and heart rate.

When the infusion is over, you'll need to stay for a couple of hours so the nurse can keep checking on you to make sure you're feeling okay.¹²

What should I bring with me?

The clinic staff can give you more specific information, but you may want to bring:⁸

- An extra sweater or blanket
- Water and snacks
- Things to keep you busy, like books, magazines, music, games, or a laptop, tablet, or phone



To help prevent the spread of COVID-19, the nurse and other clinic staff will wear masks, gloves, and face shields.¹⁰

They may also limit the time they spend near you during the infusion — but they're still there for you if you need them.

If you have any questions or concerns during the infusion process, don't hesitate to ask the clinic staff. It's their job to explain what's happening and make sure you feel comfortable.



What happens after my appointment?

In the days and weeks after your infusion, your doctor or the clinic staff will keep checking with you to see how you feel and which COVID-19 symptoms you have.

They may also ask you to come in again to do another COVID-19 test or to take samples of blood from your arm.

If you have any new symptoms or side effects, tell your doctor right away. You can also report side effects to **FDA MedWatch** at www.fda.gov/medwatch or by calling 1-800-FDA-1088.



How soon does the treatment start working?

Everyone is different, so there's no way to know for sure. In clinical trials, people who took bamlanivimab started to see their symptoms improve after about 6 days, on average, compared to 8 days for people who took an infusion with no medicine in it.⁶

Even after the treatment, you could still pass COVID-19 to other people. It's important to stay away from other people for as long as your doctor tells you to.



References

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- ⁴ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/healthyweight/bmi/calculator.html>
- ⁵ Coronavirus Prevention Network: <https://coronaviruspreventionnetwork.org/coronavirus-vaccine-and-antibody-science/>
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- ⁷ American Academy of Allergy, Asthma, and Immunology: <https://www.aaaai.org/conditions-and-treatments/library/immune-deficiencies-library/ivig>
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- ¹⁰ National Infusion Center Association: https://infusioncenter.org/infusion_resources/covid-19/
- ¹¹ Coronavirus Prevention Network: <https://coronaviruspreventionnetwork.org/coronavirus-vaccine-and-antibody-science/>
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