

What you need to know about bamlanivimab

(neutralizing antibody treatment for COVID-19)



If you've recently been diagnosed with COVID-19, you may have a new treatment option: **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 COVID-19 and this new treatment — including its possible benefits and side effects. **Together, you and your doctor can decide if this treatment could be an option for you.**

Important facts about bamlanivimab^{1,2}:

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.

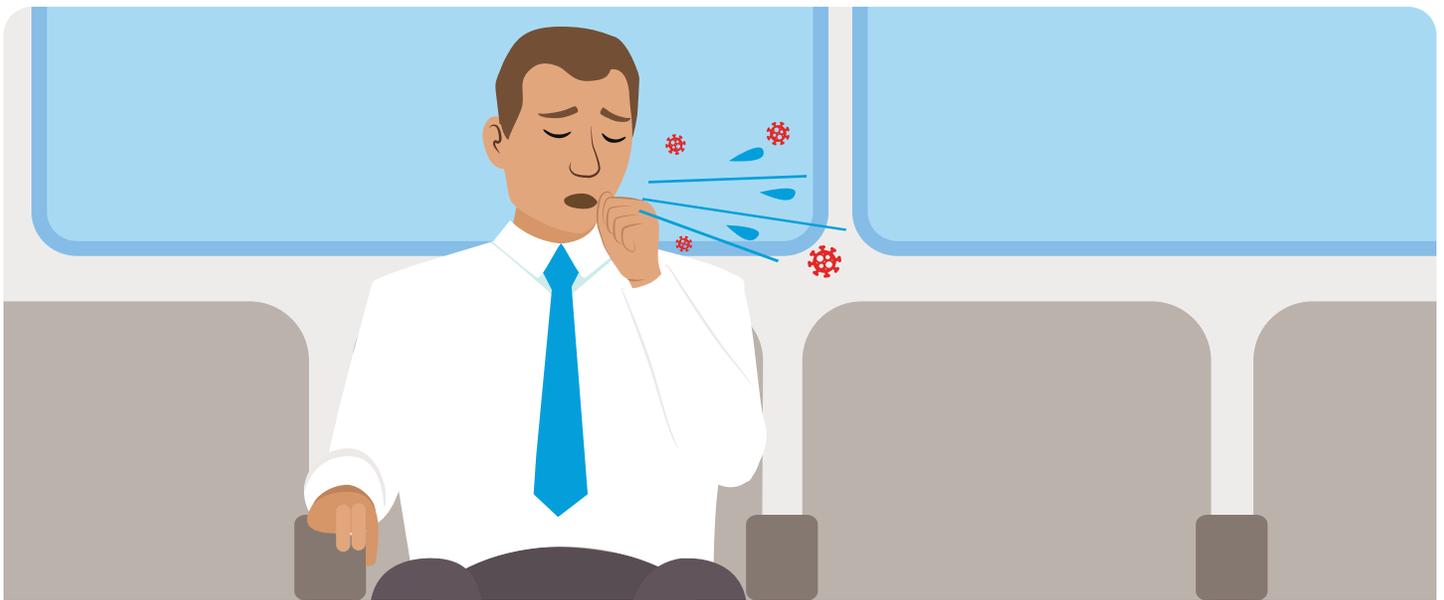
This guide is not a substitute for the official fact sheet. For information on the authorized use of bamlanivimab and mandatory requirements under the Emergency Use Authorization, please review the [FDA Letter of Authorization](#), [Fact Sheet for Healthcare Providers](#), and [Fact Sheet for Patients,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

What is COVID-19?

COVID-19 is a disease caused by a virus called SARS-CoV-2. This is a type of coronavirus. COVID-19 can cause:³

- Fever or chills
- Cough, sore throat, or trouble breathing
- Body aches or headache
- Runny or stuffy nose
- Upset stomach (nausea, vomiting, or diarrhea)
- Feeling very tired
- Loss of taste or smell

Most people with COVID-19 have mild symptoms or no symptoms at all. Other people have serious symptoms, and some even die.⁴ Older people and people with certain health conditions are more likely to get very sick from COVID-19.⁵



How does COVID-19 spread?

COVID-19 spreads easily from person to person. It mainly spreads through the air — when a person who has the disease coughs, sneezes, or talks and someone nearby breathes in their germs.⁶

What is bamlanivimab?

Bamlanivimab is a **neutralizing antibody drug**.² 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.⁷

Bamlanivimab 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 virus in your body. This could give your body more time to learn how to make its own antibodies. Bamlanivimab does not have any COVID-19 virus in it.⁶

In a clinical trial, scientists found that bamlanivimab may limit the amount of virus in the body for people with COVID-19 who take the drug within 10 days of symptoms starting. They may also be less likely to need to go to the hospital.^{1,2}

Before you take bamlanivimab, tell your doctor if you:¹

- Have any allergies
- Have any 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



Who is this drug for?

Bamlanivimab is a treatment option for people with COVID-19 who:^{1,2}

- 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

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 gender⁸
- 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

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 Patients, Parents and Caregivers](#).

How will I take this drug?

You only need to get the drug 1 time. It's an **intravenous (IV) infusion**, meaning that a nurse will put a small needle in your arm to give you the drug slowly over about 16 minutes to 1 hour.¹ Your healthcare provider will determine the duration of your infusion. The treatment is usually given at a hospital, clinic, or infusion center.^{1,2}

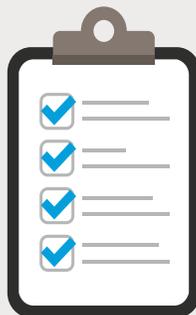
Getting any medicine through an IV can cause side effects in the area where the needle went into the skin. These may include:¹

- Pain that lasts a short time during the infusion
- Bleeding, bruising, swelling, or soreness
- Infection

Is bamlanivimab safe¹?

Scientists aren't sure yet. They're still studying bamlanivimab 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. 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.



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. Talk to your doctor about your options and your specific situation.¹

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 if your symptoms get worse, during or after your infusion. Some of these side effects may be signs of a serious allergic reaction. You can also report side effects to **FDA MedWatch** at www.fda.gov/medwatch or by calling 1-800-FDA-1088.



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.¹

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 other treatment options are there for COVID-19?

Bamlanivimab is among the first drugs given Emergency Use Authorization to treat people with COVID-19 who are newly diagnosed and have mild to moderate symptoms.^{1,9}

Your doctor may also recommend over-the-counter medicines — like pain relievers to help with fever and body aches, or cough medicine so coughing doesn't keep you awake at night. These medicines can help you feel better, but they won't help your body fight the virus or make you less likely to need to go to the hospital.¹⁰

And scientists around the world are working hard to develop new treatments to help people get better — and to end the pandemic sooner.

What about clinical trials?

You may be able to join a clinical trial for a COVID-19 treatment that doesn't have Emergency Use Authorization yet, but participating doesn't guarantee you'll get the treatment. If you're interested in joining a clinical trial, talk to your doctor.

To **learn more** about bamlanivimab or other possible COVID-19 treatments:

- Talk to your doctor
- Visit bamlanivimab.com
- Visit covid19treatmentguidelines.nih.gov
- Contact your state public health department



References

- ¹ Eli Lilly and Company: <http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-patient.pdf>
- ² Eli Lilly and Company: <http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf>
- ³ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>
- ⁴ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>
- ⁵ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>
- ⁶ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>
- ⁷ Coronavirus Prevention Network: <https://coronaviruspreventionnetwork.org/coronavirus-vaccine-and-antibody-science/>
- ⁸ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/healthyweight/bmi/calculator.html>
- ⁹ The National Institutes of Health: <https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-eua/>
- ¹⁰ U.S. Centers for Disease Control and Prevention: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>