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

If you’ve recently been diagnosed with COVID-19, your doctor may offer you a treatment that includes 2 drugs administered together: bamlanivimab (bam-la-NIV-i-mab) and etesevimab (e-te-SEV-i-mab).

The research so far shows that for certain people, getting this treatment 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. But bamlanivimab and etesevimab are unapproved drugs that are 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 treatment and what to expect before, during, and after treatment.

Important facts about bamlanivimab and etesevimab:

• **Bamlanivimab and etesevimab are investigational, which means they’re still being studied.** Bamlanivimab and etesevimab together have not been approved, but have been authorized for emergency use by the United States Food and Drug Administration (FDA) to treat mild to moderate symptoms of COVID-19 in 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 and/or the need for hospitalization.

• **FDA has authorized bamlanivimab and etesevimab for emergency use only during the COVID-19 pandemic.** Bamlanivimab and etesevimab together are authorized for the treatment of mild to moderate symptoms of COVID-19 in 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 and/or hospitalization only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of bamlanivimab and etesevimab 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 etesevimab together and mandatory requirements under the Emergency Use Authorization, please review the [FDA Letter of Authorization](https://www.fda.gov), [Fact Sheet for Healthcare Providers](https://www.fda.gov), and [Fact Sheet for Patients, Parents and Caregivers](https://www.bamandete.com) at bamandete.com.
Who is this treatment for?\textsuperscript{1,2}

Bamlanivimab and etesevimab are a treatment option for people who:

- Have a positive COVID-19 test result
- Are age 12 or older and weigh at least 88 pounds (40 kg)
- Have had mild to moderate symptoms for 10 days or less
- Are at high risk to get very sick from COVID-19

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

Am I at high risk?

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

- You are age 65 or older
- You have obesity, with a body mass index (BMI) of 35 or higher
- You have diabetes, chronic kidney disease, or a condition that weakens the immune system
- You take medication that weakens the immune system
- You are age 55 or older and have at least 1 of the following:
  - Heart disease
  - High blood pressure
  - A long-term lung disease

For adolescents (ages 12 to 17) who weigh at least 88 pounds (40 kg), bamlanivimab and etesevimab may be an option if the child meets at least one of the following criteria:

- They have obesity, with a BMI equal to or higher than 85 percent of people their age and gender\textsuperscript{4}
- They have heart disease, sickle cell disease, or a developmental condition like cerebral palsy
- They take daily medicine for asthma or another long-term lung disease
- They regularly use medical technology, like a ventilator or feeding tube

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

What is COVID-19?

COVID-19 is a disease that can cause symptoms including fever, cough, and trouble breathing. Though most people with COVID-19 get better within 2 weeks, some people are very sick for a long time — or even die.\textsuperscript{3}
What are the side effects?¹

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

- 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

Some of these side effects may be signs of a serious allergic reaction, which can be life-threatening. Tell your doctor or nurse right away if you have any side effects, or if your symptoms get worse, during or after your infusion.

After taking bamlanivimab and etesevimab together, some people had new or worsening COVID-19 symptoms including fever, trouble breathing, fast or slow heartbeat, tiredness, weakness, or confusion and some of these events have been serious and required people to go to the hospital. Scientists can’t be sure if bamlanivimab and etesevimab caused the serious symptoms or if they happened because of COVID-19.

Keep in mind that only a limited number of people have received bamlanivimab and etesevimab, and scientists are still learning about the treatment’s side effects and risks. Serious and unexpected side effects may happen.

It’s also possible that bamlanivimab and etesevimab could make it harder for your body to fight off a future COVID-19 infection — and they could make a future COVID-19 vaccine less effective for you. Scientists haven’t done specific studies to address this these possible risks. If you have any questions, talk with your doctor.
How do the drugs work?

When there’s a virus in your body, 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 and etesevimab are neutralizing antibody drugs that are taken together. That means they contain 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.⁵

Are bamlanivimab and etesevimab safe?¹

Scientists aren’t sure yet. They’re still studying these drugs 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 (EUA) for doctors to use these drugs together with certain patients even though they’re unapproved.

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

What if I’m pregnant or breastfeeding?¹

Scientists haven’t treated many pregnant or breastfeeding people with bamlanivimab and etesevimab. It’s possible that the drugs may have more benefits than risks for them and their babies. Talk to your doctor about your options and your specific situation.
How will I receive these drugs?¹,²

You only need to get the treatment 1 time. It’s usually given at a hospital, clinic, or infusion center, and the appointment takes about 2 hours — but it could be a bit shorter or longer.

The treatment is an intravenous (IV) infusion, meaning the drugs go directly into your blood. The infusion may last an hour or longer or be as short as 21 minutes. A nurse will insert a small needle into a vein in your arm to give you the drugs.

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.⁶ 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.

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.

Is this treatment 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.⁵

Antibody drugs (including bamlanivimab and etesevimab) are not vaccines. They do not have any virus in them.
How can I get ready for my appointment?

Plan for the infusion appointment to take about 2 hours, but it could be a bit longer or shorter. Most people are able to go home the same day, unless they have very serious side effects from the infusion.¹,²

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-19.⁷,⁸

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.⁹

What should I bring with me?

The clinic staff can give you more specific information, but you may want to bring:⁷

- An extra sweater or blanket
- Water and snacks
- Things to keep you busy, like books, magazines, music, games, or a laptop, tablet, or phone
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 may last an hour or longer or be as short as 21 minutes. 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 about an hour so the nurse can keep checking on you to make sure you’re feeling okay.²,⁸

To help prevent the spread of COVID-19, the nurse and other clinic staff will wear masks, gloves, and face shields.⁹ 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](http://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 and etesevimab started to see their symptoms improve after about 6 days, on average, compared to 8 days for people who got an infusion with no medicine in it.

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

4 U.S. Centers for Disease Control and Prevention: [https://www.cdc.gov/healthyweight/bmi/calculator.html](https://www.cdc.gov/healthyweight/bmi/calculator.html)
7 National Infusion Center Association: [https://infusioncenter.org/how-to-prepare-for-your-infusion/](https://infusioncenter.org/how-to-prepare-for-your-infusion/)
9 National Infusion Center Association: [https://infusioncenter.org/infusion_resources/covid-19/](https://infusioncenter.org/infusion_resources/covid-19/)