

Emergency Use Authorization (EUA) of Bamlanivimab for COVID-19 Fact Sheet for Patients, Parents and Caregivers

You may be receiving a medicine called **bamlanivimab** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab, which you may receive.

- Receiving bamlanivimab may benefit certain people with COVID-19.
- Read this Fact Sheet for information about bamlanivimab. Talk to your healthcare provider if you have questions. It is your choice to receive bamlanivimab or stop it at any time.

What is COVID-19?

COVID-19 is caused by the coronavirus SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus. COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, seem to be at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What is bamlanivimab?

Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Bamlanivimab is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab to treat people with COVID-19. The FDA has authorized the emergency use of bamlanivimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA).

What is an Emergency Use Authorization (EUA)?

The United States FDA has made bamlanivimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. Bamlanivimab has not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

I have a positive test for SARS-CoV-2, the virus that is responsible for COVID-19 illness, and I am interested in this monoclonal antibody medication.

- **Contact your doctor's office** to inquire about this medication and determine if you may be eligible for consideration. Not everyone is eligible based on the prescribing criteria outlined by the FDA. Further, given the extremely limited supply of medication, not all eligible patients will have access to the medication.
 - Patients who require hospitalization or require oxygen therapy (or increased oxygen if on chronically at baseline) for COVID-19 may not be considered for this medication.

- Safety is not known in pregnant or breast-feeding women.
- The medication must be given within 10 days from symptom onset.
- Eligibility criteria include:
 - Are ≥ 65 years old
 - Have a Body Mass Index ≥ 35
 - Have a Compromised immune system due to underlying illness or medication
 - Have Chronic kidney disease
 - Have Diabetes
 - Are ≥ 55 years old AND have one of the following
 - Cardiovascular disease
 - Hypertension
 - Chronic respiratory disease (e.g. COPD)
 - Are 12-17 years old AND have one of the following:
 - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
 - Sickle cell disease, OR
 - Congenital or acquired heart disease, OR
 - Neurodevelopmental disorders, for example, cerebral palsy, OR
 - A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
 - Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
- If you are eligible, and after discussion with your healthcare provider, the decision is made to try to obtain the medication for treatment, your provider will enter your information into a Colorado statewide system that randomly selects patients who can receive the medication. This process has is being used to ensure that each patient can have an equal chance to access the medication.
 - If you are not selected, then you will not receive the medication.
 - If you are selected, you will have access to schedule an infusion based on available locations.

What should I tell my healthcare provider before I receive bamlanivimab?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How will I receive bamlanivimab?

- Your prescriber will enter your information in to the State Random Allocation System.
- If you are selected to receive the medication, you must do so within 10 days from start of symptoms.
- Bamlanivimab is given to you through a vein (intravenous or IV) for at least 1 hour.
- You will receive one dose of bamlanivimab by IV infusion.

What are the important possible side effects of bamlanivimab?

Possible side effects of bamlanivimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied so it is possible that all of the risks are not known at this time. It is possible that bamlanivimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?

Like bamlanivimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.covid19treatmentguidelines.nih.gov/> for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for. It is your choice to be treated or not to be treated with bamlanivimab. Should you decide not to receive bamlanivimab or stop it at any time, it will not change your standard medical care.

How do I report side effects with bamlanivimab?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away. Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921).

How can I learn more?

- Ask your healthcare provider
- Visit www.bamlanivimab.com
- Visit <https://www.covid19treatmentguidelines.nih.gov/>
- Contact your local or state public health department

The EUA for bamlanivimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the product may no longer be used). Literature issued November 2020 **Eli Lilly and Company, Indianapolis, IN 46285, USA** Copyright © 2020, Eli Lilly and Company. All rights reserved. 5.0-BAM-0000-EUA PAT-20201109