



Lilly Bamlanivimab Antibody Playbook

ELI LILLY AND COMPANY | NOVEMBER 2020

For the Emergency Use Authorization of bamlanivimab for the treatment of COVID-19

The Secretary of the Department of Health and Human Services has declared a public health emergency that justifies the emergency use of bamlanivimab to treat coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 infection. In response, the US Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the unapproved product, bamlanivimab, for the treatment of COVID-19.

- Bamlanivimab has not been approved, but has been authorized for emergency use by FDA, to treat mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- Bamlanivimab is authorized for the treatment of mild to moderate COVID19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, 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 the 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.
- The FDA issued this EUA, requested by Eli Lilly and Company and based on their submitted data. Find more information in the [FDA Letter of Authorization](#).
- Health care providers should review the Fact Sheet for information on the authorized use of bamlanivimab and mandatory requirements of the EUA.
- Health care providers should review the [Fact Sheet for Healthcare Providers](#) for important information on the use of bamlanivimab.

SECTION 06

**EDUCATION
AND AWARENESS**

EDUCATION AND AWARENESS

Attacking the coronavirus will require a diverse set of approaches, including both vaccines and treatments, such as antibodies.

Q. What's the difference between vaccines and monoclonal antibody drugs?

A. While there are some similarities, here's how they are different:

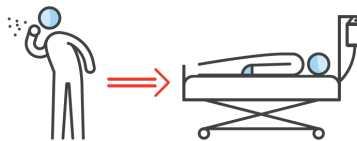
- Monoclonal antibody drugs, like bamlanivimab, provide passive immunity by giving the body antibodies to protect itself. Vaccines provide active immunity by helping the body make its own antibodies to protect itself.
- Monoclonal antibody drugs are designed to start working faster than vaccines, while protection provided by vaccines will generally last longer.
- Generally, scientists are able to develop antibody treatments faster than they are able to develop vaccines.

Developing any approach against COVID-19 involves assessing key factors:



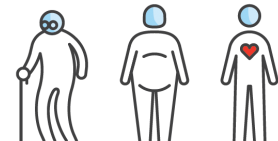
Viral exposure

A vaccine will not help an already-infected patient



Stage of disease

When to apply the medicine to prevent the infection or treat the disease

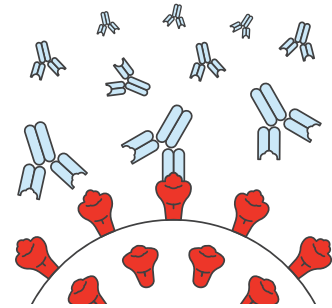


At-risk populations

Factors linked to worse outcomes (e.g., age, concurrent diseases)

NEUTRALIZING ANTIBODIES AS POTENTIAL TREATMENTS

Identified and characterized using various methods, including from the blood of COVID-19 survivors, neutralizing antibodies target the viral spike protein that SARS-CoV-2 uses to gain entry into host cells. Neutralizing antibodies, therefore, are specifically designed to treat COVID-19.



Q. What are antibodies?

A. Antibodies are naturally made in our bodies to fight infection.

- Whenever the immune system meets a new foreign substance in the body, it makes new antibodies that attack the foreign substance. The next time that substance shows up, the immune system can produce the same antibodies to help the body fight it off before it can make a person sick. These types of naturally occurring antibodies provide active immunity.
- Vaccines work in a similar way, helping the body make antibodies to attack specific foreign substances and providing active immunity in the body.
- Antibody drugs are different. They are man-made antibodies that are given directly through an infusion or injection rather than prompting the body to make the antibodies for itself. This type of immunity is called passive immunity.

Find more information about monoclonal antibody drugs and vaccines from the CDC, State Health Departments, and the following resources:

- www.coronaviruspreventionnetwork.org
- www.infusioncenter.org/
- [Fact Sheet for Healthcare Providers](#)
- [Fact Sheet for Patients, Parents and Caregivers \(English\)](#)
- [Fact Sheet for Patients, Parents and Caregivers \(Spanish\)](#)
- [FDA Letter of Authorization](#)

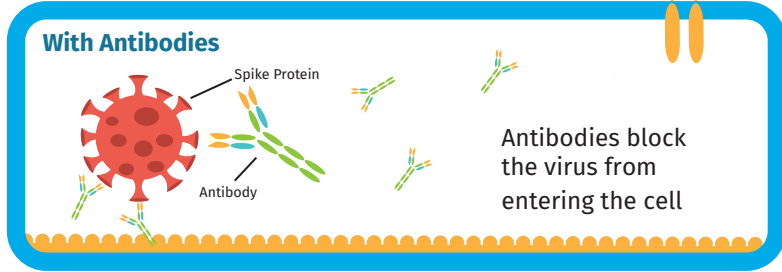
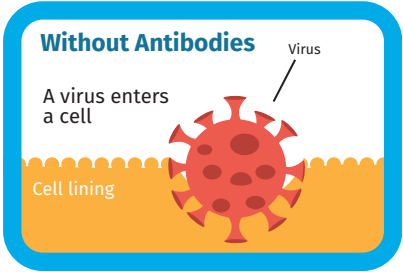


Monoclonal Antibodies



What are antibodies?

Antibodies are naturally made in our bodies to fight infection.



What are MONOCLONAL ANTIBODIES?



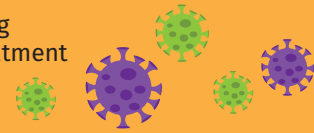
Monoclonal antibodies (**mAbs**) are antibodies developed in a laboratory to help our bodies fight infection.

Nearly
100

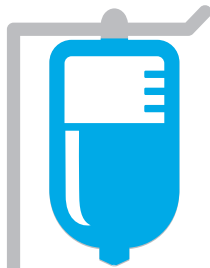
mAbs are FDA approved to treat health conditions including cancers and autoimmune diseases.



mAbs are also being studied for the treatment and prevention of COVID-19.



How are mAbs administered?



mAbs are given through intravenous infusion (i.e., through a vein) or injection.

OR



How often infusions or injections of mAbs are needed depends on the specific mAbs.

What are common side effects of mAbs?



Allergic reactions



Flu-like Symptoms



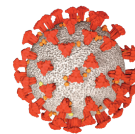
Nausea & Vomiting



Diarrhea



Low blood pressure



COVID-19
Prevention Network
PreventCOVID.org

ama-assn.org cancer.org mayoclinic.org medicinenet.com nature.com synabs.be uptodate.com