

Emergency Use Authorization of Bamlanivimab for COVID-19

11/16/2020

On 11/9/20, the Food and Drug Administration (FDA) authorized Bamlanivimab for treatment of recently diagnosed, mild to moderate COVID-19 in high-risk patients. Eligible patients must have certain risk factors, such as diabetes or heart disease that increases their risk of severe COVID-19 complications.

The FDA has authorized its use for the treatment of COVID-19 under an Emergency Use Authorization (EUA) during the study. The FDA authorized the EUA because patients treated with Bamlanivimab showed reduced viral load and reduced rates of symptoms and hospitalization. However, there is limited information known about the safety or effectiveness of using Bamlanivimab to treat people with COVID-19.

About Bamlanivimab

Bamlanivimab is a monoclonal antibody therapy for treating COVID-19. Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as SARS-CoV-2, the virus that causes COVID-19.

Bamlanivimab is used in non-hospitalized adults and adolescents who are 12 years of age and older with mild to moderate symptoms, weigh 88 pounds (40 kg) or more, and are at high risk for developing severe COVID-19 symptoms or the need for hospitalization.

While using Bamlanivimab may prevent the need for hospitalization, it must be administered early in the course of COVID-19. Administer Bamlanivimab as soon as possible after a positive COVID-19 test and no longer than 10 days after symptom onset or your test date.

Possible benefits of Bamlanivimab

Recent studies show Bamlanivimab, when given early in the disease, may help reduce COVID-related hospitalizations. The recently completed Phase 2 study showed that in patients at high risk for disease progression and hospitalizations/emergency room visits, COVID-19 occurred in 3% of Bamlanivimab treated patients on average, compared to 10% in patients who received a placebo, a dose with no medicine in it.

Possible risks of Bamlanivimab

- The therapy is administered as an IV infusion and is only for outpatients.
- Recent studies show possible side effects of Bamlanivimab include allergic reactions; specifically 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. There may be other side effects of Bamlanivimab.
- As it is an antibody treatment, it is possible that Bamlanivimab could interfere with the patient's own immune response to future infections with SARS-CoV-2 or a vaccine for COVID-19.

Bamlanivimab supply in Minnesota

The U.S. Government purchased 300,000 doses of Bamlanivimab, and is currently distributing doses nationwide. Allocations from the U.S. Government will be coming to Minnesota weekly. Supply may be scarce initially, but should increase over the coming weeks. While there is no cost to hospitals or to health systems for the drug itself, there are other associated costs such as IV supplies and other facility costs that may carry a charge.

The Minnesota Department of Health (MDH) is working with the MN COVID-19 Ethics Collaborative, the MDH Science Advisory Team, and an advisory group of infectious disease specialists, to determine how to allocate the supply. MDH is also working with the Minnesota Hospital Association, regional health care coalitions, and other health care partners to develop a distribution plan so that patients in each region of the state will have access to this therapy.

What to do next

- Ask your health care provider about all your treatment choices, including Bamlanivimab.
- Tell your health care provider if you experience any symptoms during your infusion such as nausea, swelling of your lips or tongue, rash or shortness of breath.
- Tell your health care provider if you develop any new symptoms after your infusion, even if it is hours or days later.

More information

Ask your health care provider for more information about Bamlanivimab. Information is also available below.

- [FDA: Frequently Asked Questions, \(https://www.fda.gov/media/143605/download\)](https://www.fda.gov/media/143605/download)

EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB

- [U.S. Department of Health and Human Services: Public Health Emergency, \(https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/default.aspx\).](https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/default.aspx)



Minnesota Department of Health | health.mn.gov | 651-201-5000
625 Robert Street North PO Box 64975, St. Paul, MN 55164-0975

Contact health.communications@state.mn.us to request an alternate format.