Yale NewHaven Health

Bamlanivimab or Casirivimab/Imdevimab
Patient Information

Your doctor has recommended that you receive a medication called **bamlanivimab** or **casirivimab/imdevimab** for the treatment of coronavirus disease 2019 (COVID-19).

The U.S. Food and Drug Administration has authorized the emergency use of bamlanivimab and carsirivimab/imndevimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section "**What is an Emergency Use Authorization (EUA)?**" at the end of this fact sheet*.

This fact sheet contains information to help you understand the potential risks and benefits of taking this medication.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. 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.

Older adults and people of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, are at a 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 which can result in hospitalization.

What are bamlanivimab and casirivimab/imdevimab?
Both are medicines 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.

These medicines are antibodies that work against a protein needed by the virus, which causes COVID-19 to enter cells in the body. These antibodies bind to this protein that prevents the virus from infecting cells in your body. The antibodies are called "monoclonal antibodies" which means they are specifically manufactured in a laboratory for this purpose; they are NOT derived from human blood products.

What is the potential benefit of receiving bamlanivimab or casirivimab/imdevimab?
Both medicines have been studied in outpatients with mild to moderate COVID-19 infection and reduced the need for hospitalization compared to patients who received an infusion without the medicine (what is commonly called a placebo).

Of the two medicines, which one will I receive?
Both medicines, bamlanivimab and casirivimab/imdevimab, work in the same fashion and are equally effective. The supply of each medicine is limited at this time, so which one you will receive will depend on the availability of the drug at the time of infusion.

What should I tell my healthcare provider before I receive bamlanivimab or carisivimab/imdevimab?
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)
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What are the important possible side effects of bamlanivimab or casirivimab/imdevimab?

- 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 or casirivimab/imdevimab. Serious and unexpected side effects may happen. Bamlanivimab and casirivimab/imdevimab are still being studied so it is possible that all of the risks are not known at this time.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab or casirivimab/imdevimab. For a mother and unborn baby, the benefit of receiving bamlanivimab or casirivimab/imdevimab may be greater than the risk from the treatment.
If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How will I receive bamlanivimab or casirivimab/imdevimab?

- Bamlanivimab or casirivimab/imdevimab is given as an outpatient at a Yale New Haven Health System location.
- You must have someone drop you off and pick you up.
- Expect to be there 3 hours. You must wear a mask at all times
- You will receive one dose of bamlanivimab or casirivimab/imdevimab through a vein (intravenous or IV infusion).
- You will be monitored for possible side effects for another hour after the infusion has ended.
- If you need to cancel or change your appointment, call scheduling at 203-680-7143.

***What is an Emergency Use Authorization (EUA)?**
The United States FDA has made bamlanivimab or casirivimab/imdevimab 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 and casirivimab/imdevimab have 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 the product to be used in the treatment of patients during the COVID-19 pandemic.