Yale NewHaven Health

Bamlanivimab/Etesevimab or Casirivimab/Imdevimab
Physician guidance for outpatient education

The U.S. Food and Drug Administration (FDA) has authorized the emergency use of bamlanivimab/etesevimab and casirivimab/imdevimab 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.*

What are bamlanivimab/etesevimab 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 which then 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/etesevimab 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).

Who is eligible to receive bamlanivimab/etesevimab or casirivimab/imdevimab?
Patients must be at least 12 years of age, weigh at least 40 kg and have a documented positive result of a direct SARS CoV-19 viral test within the last 10 days AND meet the following clinical criteria listed below:

1. Patients ≥ 65 years of age
2. Patients ≥ 55 years of age AND have one of the following comorbidities:
    a. Chronic obstructive pulmonary disease/other chronic respiratory disease
3. Patients of any age with one of the following co-morbidities:
    a. Diabetes mellitus
    b. BMI ≥ 35 kg/m2
    c. Chronic Kidney Disease
    d. Congestive Heart Failure
    e. Severe pulmonary disease defined as one of the following:
        i. COPD with continuous home oxygen, pulmonary hypertension/pulmonary fibrosis, or cystic fibrosis
    f. Cirrhosis
    g. Immunosuppressed status due to an underlying immunocompromising condition or use of immunosuppressive therapy
    h. Sickle cell disease
    i. Parkinson's disease
4. Patient aged 12-17 with one of the following:
    a. Congenital or acquired heart disease
    b. Neurodevelopmental disorders
    c. Medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
    d. Chronic respiratory disease excluding asthma

Of the two medicines, which one will the patient receive?
Both medicines, bamlanivimab/etesevimab 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 are the important possible side effects of bamlanivimab/etesevimab or casirivimab/imdevimab?
Possible side effects are:

- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab/etesevimab or casirivimab/imdevimab.
- Such reactions are rare but include 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/etesevimab or casirivimab/imdevimab. Serious and unexpected side effects may happen. Bamlanivimab/etesevimab and casirivimab/imdevimab are still being studied so it is possible that all of the risks are not known at this time.

What if the patient is pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab/etesevimab or casirivimab/imdevimab. For a mother and unborn baby, the benefit of receiving bamlanivimab/etesevimab or casirivimab/imdevimab may be greater than the risk from the treatment.

How will bamlanivimab/etesevimab or casirivimab/imdevimab be administered?

- Bamlanivimab/etesevimab 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 2 hours. You must wear a mask at all times
- You will receive one dose of bamlanivimab/etesevimab 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 are the recommendations for receiving bamlanivimab/etesevimab or casirivimab/imdevimab and the COVID-19 vaccine?
The COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy.

***What is an Emergency Use Authorization (EUA)?**
The US FDA has made bamlanivimab/etesevimab 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/etesevimab 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 for the product to be used in the treatment of patients during the COVID-19 pandemic.