

Casirivimab/Imdevimab

Physician guidance for outpatient education

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

What is casirivimab/imdevimab?

It is a 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.

The medicine contains 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 casirivimab/imdevimab?

The medication has 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 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) Patient is ≥ 65 years of age
- OR

Patients with ANY of the following co-morbidities:

- 2) Obesity or overweight (BMI > 25 kg/m² or age 12-17 or have BMI ≥ 85 th percentile for their age & gender based on CDC growth charts)
- 3) Diabetes mellitus
- 4) Cardiovascular disease (including hypertension or congenital heart disease)
- 5) Chronic lung disease (e.g., COPD, moderate to severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension)
- 6) Chronic kidney disease
- 7) Immunosuppressive disease or immunosuppressive treatment
- 8) Pregnancy
- 9) Cirrhosis
- 10) Parkinson’s disease
- 11) Sickle cell disease
- 12) Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and congenital abnormalities)
- 13) Having medical-related technology dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-10])

What are the important possible side effects of casirivimab/imdevimab?

Possible side effects are:

- Allergic reactions.
Allergic reactions can happen during and after infusion with 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 casirivimab/imdevimab. Serious and unexpected side effects may happen. Casirivimab/imdevimab is 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 casirivimab/imdevimab. For a mother and unborn baby, the benefit of receiving casirivimab/imdevimab may be greater than the risk from the treatment.

How will casirivimab/imdevimab be administered?

- 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 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 the recommendation for receiving casirivimab/imdevimab and a COVID-19 vaccine?

The COVID-19 vaccine should be deferred for at least 90 days for persons who received passive antibody therapy such as casirivimab/imdevimab.

***What is an Emergency Use Authorization (EUA)?**

The US FDA has made 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.

Casirivimab/imdevimab 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.