

Monoclonal Antibody Treatment for COVID-19

Updated: 8/21/2021

Overview

In November, 2020, the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUA) permitting the use of Eli Lilly's Bamlanivimab and Regeneron's Casirivimab and Imdevimab monoclonal antibodies. Both treatments are permitted for the treatment of mild to moderate COVID-19 in outpatient adult and pediatric patients. The EUAs for these treatments do not authorize their use for patients who are hospitalized due to COVID-19 or who require oxygen therapy due to COVID-19.

What are monoclonal antibodies (mAbs) and how do they work?

An antibody is a protein that the body's immune system makes to fight off viruses and other foreign substances. Monoclonal antibodies are man-made antibodies produced in a laboratory that can mimic the human immune system response to infection. Each of the three drugs given an EUA are designed to block viral attachment and entry into human cells, thus neutralizing the virus that causes COVID-19. Casirivimab and imdevimab must be given together, and bamlanivimab is given by itself.

How are mAbs given?

MABs must be given by intravenous (IV) infusion. Therefore, mAbs may only be administered in settings in which health care providers have immediate access to medications to treat severe infusion reactions, such as allergic reaction, and the ability to activate the emergency medical system, as necessary.

Who may receive mAbs?

Under the terms of the EUAs, mAbs may be used for the treatment of mild to moderate COVID-19 in adults and pediatric patients who meet all of the following:

- Have a positive test for SARS-CoV-2 (molecular/PCR or antigen)
- Are within 10 days of the start of their symptoms
- Are at least 12 years of age or older and weigh at least 40 kilograms (88 pounds)
- Are at a high risk for progressing to severe COVID-19 and/or hospitalization

Who is considered "high risk"?

High risk for progressing to severe COVID-19 and/or hospitalization is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) greater than 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are 65 years of age or older
- Are 55 years of age or older AND have one or more of the following:
 - Cardiovascular disease
 - Hypertension

- Chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12-17 years of age AND have one or more of the following:
 - BMI greater than the 85th percentile for their age and gender, based on [clinical growth charts](#)
 - Sickle cell disease
 - Congenital or acquired heart disease
 - Neurodevelopment disorders, for example, cerebral palsy
 - A medical-related technological dependence; for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
 - Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

Can individuals who are pregnant or breastfeeding receive mAbs?

Currently, mAbs have not been sufficiently studied to make a recommendation for use while pregnant. Fact sheets for both treatments state that they “should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.”

Similarly, there is no available data on the presence of mAbs in human or animal milk, the effects on the breastfed infant, the effects on milk production, or on possible health effects from breast milk.

Individuals who are pregnant or breastfeeding, and meet treatment criteria, should discuss the use of mAbs with their physician.

Who should not receive mAbs?

MABs may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation. Under the terms of the EUA mAbs are not authorized for use in patients who meet any of the following:

- Are hospitalized due to COVID-19
- Require oxygen therapy due to COVID-19
- Require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Cost to patients

There is no cost to patients as the medications are made available to providers at no cost. Providers can bill the patient’s insurance carrier for a facility/service charge to the patients insurance but they cannot bill patients.

Cost to providers

Insured Patients: The medications are made available at no cost to the provider. For their patients with insurance including Medicare and Medicaid, providers can bill for the office visit.

Uninsured Patients: For uninsured patients, the federal HRSA COVID-19 Coverage Assistance Fund was developed to reimburse providers for COVID-19 treatments including monoclonal antibody therapy. See this link for more information: <https://www.hrsa.gov/coviduninsuredclaim>

More information for providers

- [Fact Sheet for Health Care Providers: EUA of Bamlanivimab](#)
- [Fact Sheet for Health Care Providers: EUA of Casirivimab and Imdevimab](#)

How to Find a monoclonal antibody provider/location

A listing of Louisiana healthcare facilities that have received mAbs can be found in LDH's [December 23, 2020, HAN](#).

Searchable Map: The federal government has developed a searchable national map that show locations that have received shipments of monoclonal antibody therapeutics under the U.S. Food and Drug Administration Emergency Use Authorization (EUA) authority, within the past several weeks. The scalable map is found at this link: <https://protect-public.hhs.gov/pages/therapeutics-distribution>.

Telephone Hotline: A call center is available to answer questions and provide information related to monoclonal antibody therapeutic treatments at 1-877-332-6585 (English Language); 1-877-366-0310 (Spanish Language).

How do I get treated with monoclonal antibody therapy?

Patients need to be referred by their doctor or other healthcare provider to a facility that offers mAb therapy such as a hospital or an infusion center.

Patients with a positive COVID-19 viral test should speak with their healthcare provider to determine whether they are eligible for mAb treatment and to discuss potential benefits and side effects.