



# High-Risk COVID-19 Patients May Avoid Hospitalization with Monoclonal Antibody Treatment

## Is My Patient Eligible for Treatment?

On May 14, 2021, the FDA updated the Emergency Use Authorizations for COVID-19 monoclonal antibodies. These updates expand the definition of “high-risk” patients who are eligible for treatment and provide greater latitude to healthcare providers to exercise their clinical judgment.

- Clinicians may now refer any adult or pediatric (age 12 years and older and  $\geq 40$  kg) patient if they have a medical condition or other factor, including race/ethnicity, that puts them at higher risk for progressing to severe COVID-19.
- Eligibility is not limited to the medical conditions and factors listed below.
- For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

## **Your patient may be eligible for monoclonal antibody treatment if they meet the following criteria<sup>1</sup>:**

- Are an adult or pediatric ( $\geq 12$  years of age and weighing at least 40 kg) patient
- Experienced the **onset in the last 10 days** of mild to moderate symptoms of COVID-19
- Have a positive test for COVID-19
- Are at high risk for progressing to severe COVID-19 and/or hospitalization; high-risk factors include but are not limited to:
  - Age  $\geq 65$  years of age
  - Obesity or being overweight based on CDC clinical growth charts<sup>2</sup>
  - Pregnancy
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease or immunosuppressive treatment
  - Cardiovascular disease or hypertension
  - Chronic lung diseases
  - Sickle cell disease
  - Neurodevelopmental disorders
  - Having a medical-related technological dependence (for example: tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19)

For more detail on the eligibility criteria for the authorized treatments, see the Fact Sheets on the FDA website.<sup>1</sup>

To guide treatment decisions, you should:

- Review the antiviral resistance information in Section 15 of the authorized fact sheets<sup>1</sup> for each monoclonal antibody therapy available under EUA for details on specific variants and resistance, and
- Refer to the CDC website, as well as information from state and local health authorities, for reports of viral variants in their region.<sup>3</sup>





## **Early Action Is Vital**

Early testing, identification, and referral are vital to access to monoclonal antibody treatment. So, consider:

- Discussing monoclonal antibodies, the importance of reporting symptoms, and COVID-19 testing with your high-risk patients during routine care appointments
- Pre-identifying patients who may be eligible for monoclonal antibody treatment

Your patient is **not** eligible for treatment if they:

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

## **How to Find Infusion Locations**

You can find infusion locations in your area:

- by visiting <https://protect-public.hhs.gov/pages/therapeutics-distribution>, OR
- by calling **1-877-332-6585** for English, or **1-877-366-0310** for Spanish

Contact the infusion location(s) to learn their referral procedures and whether they are accepting new patients.

For more information, visit  
**CombatCOVID.hhs.gov**

English: 1-877-332-6585 • Spanish: 1-877-366-0310



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### **References**

1. FACT SHEETS FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB AND ETESEVIMAB (revised March 14, 2021) and CASIRIVIMAB AND IMDEVIMAB  
<https://www.fda.gov/media/145802/download>  
<https://www.fda.gov/media/145611/download>
2. CLINICAL GROWTH CHARTS. Centers for Disease Control and Prevention.  
[https://www.cdc.gov/growthcharts/clinical\\_charts.htm](https://www.cdc.gov/growthcharts/clinical_charts.htm)
3. Variant Proportions in the U.S. (May 11, 2021). Centers for Disease Control and Prevention.  
<http://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html>

