



The Science Behind Monoclonal Antibodies for COVID-19: Frequently Asked Questions

Q: What monoclonal antibody treatments are authorized for use?

A: The U.S. Food and Drug Administration (FDA) has granted emergency use authorizations (EUAs) for the following monoclonal antibodies to treat patients with mild to moderate COVID-19 and who are at high risk of developing severe symptoms. The first two are available at no cost. These treatments include:

- **REGEN-COV™ (Casirivimab and Imdevimab):** [Fact Sheet](#)¹ and [EUA](#)²
- **Bamlanivimab and Etesevimab:** [Fact Sheet](#)³ and [EUA](#)⁴
- **Sotrovimab:** [Fact Sheet](#)⁵ and [EUA](#)⁶

Q: What methods of administration are available?

A: The FDA has authorized intravenous (IV) infusion of monoclonal antibody treatments for emergency use. IV infusion is strongly recommended. The FDA also authorized subcutaneous injection for certain monoclonal antibody treatments that are currently available.² Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment.

The NIH COVID-19 Treatment Guidelines Panel recommends (AIIa) using one of these combination anti-SARS-CoV-2 monoclonal antibodies to treat outpatients with mild to moderate COVID-19 who are at high risk of clinical progression, as defined by the Emergency Use Authorization.⁷

Rating of Recommendations:

A = Strong; **B** = Moderate; **C** = Optional

Rating of Evidence:

- I** = One or more randomized trials without major limitations
- IIa** = Other randomized trials or subgroup analyses of randomized trials
- IIb** = Nonrandomized trials or observational cohort studies
- III** = Expert opinion





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Q: Which patients can be treated with the authorized monoclonal antibodies?

A: Monoclonal antibodies are authorized for the treatment of mild to moderate COVID-19 in adult or pediatric (age 12 years and older and \geq 40 kg) patients with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.^{1,3,5} Treatment must be given within 10 days of symptom onset, so it is critical to identify eligible patients at the point of diagnosis and inform them about the availability of monoclonal antibody treatment.^{8,9}

Q: What data supported the Emergency Use Authorization of the monoclonal antibodies?

A: Data from controlled clinical trials that showed that high-risk patients who received monoclonal antibodies had a decrease in the risk of progression to severe disease, hospitalization, or death compared to patients who received placebo was used in support of the EUA.^{1,3,5} The safety and efficacy of these therapies for use in the treatment of COVID-19 continue to be evaluated.

During certain types of emergencies,¹⁰ the FDA may permit authorization based on the best available evidence to provide timely access to critical care when there are no adequate, approved, and available alternatives. This may include authorization of investigational products based on significantly less data than would be required for approval by the FDA.

Q: Are monoclonal antibodies effective against new SARS-CoV-2 variants?

A: The science on this question is evolving. Some circulating SARS-CoV-2 variants may be associated with resistance to monoclonal antibodies. The FDA recently authorized updates to the fact sheets for healthcare providers, including Antiviral Resistance information in Section 15 of the fact sheets for each of the currently available treatments under emergency use. For further information, please reference the information on CDC variant classifications and definitions.¹¹

Q: How do SARS-CoV-2 variants impact treatment decisions?

- A:** To guide treatment decisions, healthcare providers should:
- Review the Antiviral Resistance information in Section 15 of the authorized fact sheets for each monoclonal antibody therapy available under EUA¹⁰ for details on specific variants and resistance.
 - Refer to the CDC website,¹² as well as information from state and local health authorities, for reports of viral variants in their region.





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For more information, visit
CombatCOVID.hhs.gov

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