# 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 monoclonal antibodies to treat patients with mild to moderate COVID-19 and who are at high risk of developing severe symptoms. These treatments include:

- **REGEN-COV™ (Casirivimab and Imdevimab):** Fact Sheet[1] (revised version, March 18, 2021) and EUA[2] (reissued February 3, 2021 and February 25, 2021)
- **Bamlanivimab and Etesevimab:** Fact Sheet[3] (revised version, March 18, 2021) and EUA[4] (reissued February 25, 2021)

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.[5]

**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

**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 adults and pediatric patients (12 years of age and older and weighing at least 40 kg) 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. 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.[6]

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

**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] The safety and efficacy of these therapies for use in the treatment of COVID-19 continue to be evaluated.

During certain types of emergencies[7], 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 updated the Antiviral Resistance information in Section 15 for each of the currently available treatments under emergency use. For further information, please reference:

- The FDA Center for Drug Evaluation and Research statement[8]
- Information on CDC variant classifications and definitions[9]

**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 EUA[10] for details on specific variants and resistance.
- Refer to the CDC website[11], as well as information from state and local health authorities, for reports of viral variants in their region.

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

For more information, visit
**CombatCOVID.hhs.gov**
English: 1-877-332-6585 • Spanish: 1-877-366-0310

COMBATCOVID

## References


1. Center for Drug Evaluation and Research (CDER). (2021, March 18). Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab with imdevimab). U.S. Food and Drug Administration. https://www.fda.gov/media/145611/download
2. Center for Drug Evaluation and Research (CDER). (2021, February 25). REGEN-COV (casirivimab and imdevimab) EUA Letter of Authorization. U.S. Food and Drug Administration. https://www.fda.gov/media/145610/download
3. Center for Drug Evaluation and Research (CDER). (2021, March 18). Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of bamlanivimab and etesevimab. U.S. Food and Drug Administration. https://www.fda.gov/media/145802/download
4. Center for Drug Evaluation and Research (CDER). (2021, February 25). Bamlanivimab and Etesevimab EUA Letter of Authorization. U.S. Food and Drug Administration. https://www.fda.gov/media/145801/download
5. Statement on Anti-SARS-CoV-2 Monoclonal Antibodies EUA. (2021, April 8). COVID-19 Treatment Guidelines. https://www.covid19treatmentguidelines.nih.gov/statement-on-anti-sars-cov-2-monoclonal-antibodies-eua/
6. Assistant Secretary for Public Affairs (ASPA). (2021, March 26). How Do I Know if I'm High-Risk, and What Do I Do Next? CombatCOVID.hhs.gov. https://combatcovid.hhs.gov/i-have-covid-19/how-do-i-know-if-im-high-risk
7. Office of the Commissioner. (2021, March 24). Emergency Use Authorization. U.S. Food and Drug Administration. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
8. Center for Drug Evaluation and Research. (2021, March 18). FDA authorizes revisions to fact sheets to address SARS-CoV-2 variants for monoclonal antibody products under emergency use authorization. U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-revisions-fact-sheets-address-sars-cov-2-variants-monoclonal-antibody-products-under
9. SARS-CoV-2 Variant Classifications and Definitions. (2020, February 11). Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html
10. Office of the Commissioner. (2021, March 24). Emergency Use Authorization. U.S. Food and Drug Administration. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
11. Variant Proportions in the U.S. (2020, February 11). Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html