

# Outpatient Management of Acute COVID-19 with Monoclonal Antibodies (mAbs)



Updated: September 13, 2021



## Background

Monoclonal antibodies (mAbs) can be used to treat patients with mild to moderate symptoms of COVID-19, and as a post-exposure prophylactic to prevent illness after being exposed to someone who has had COVID-19.

The [NIH COVID-19 Treatment Guidelines](#) recommends providing supportive care and symptomatic management to outpatients with COVID-19. For patients who are at high risk for disease progression, the panel recommends administering anti-SARA-CoV-2 antibody-based therapies.

There are three combinations of monoclonal antibodies (mAbs) available through FDA Emergency Use Authorization (EUA) for non-hospitalized patients<sup>1</sup>:

- [casirivimab plus imdevimab](#) (Regeneron)
- [Sotrovimab](#) (GlaxoSmithKline)
- [bamlanivimab plus etesevimab](#) (Eli Lilly)

mAbs for COVID-19 are designed to block viral attachment and entry into human cells, thus neutralizing the virus.

In Phase 3 clinical trials, treatment of COVID-19 with mAbs was shown to reduce the relative risk of hospitalizations or death by more than 70% in newly diagnosed COVID-19 patients who were not hospitalized.

Source: [Clinical Trials Arena](#)

## Eligibility

### Inclusion

Patients who are at high risk for progressing to severe COVID-19 and/or hospitalization meet one of the following:

- Adults and pediatric patients (age 12-17 years and  $\geq 40$ kg)
- Are overweight or obese (e.g., BMI  $>25$  kg/m<sup>2</sup> or BMI  $\geq 85$ th percentile based on age/gender guidelines<sup>2</sup>)
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (congenital or acquired), hypertension
- Chronic lung diseases (chronic obstructive pulmonary disease, moderate to severe asthma, cystic fibrosis, or other chronic respiratory disease)
- Medical-related technological dependence not related to COVID-19 (e.g., tracheostomy, gastrostomy, or positive pressure ventilation)
- Individuals who are not fully vaccinated or people with immunocompromising conditions who are not expected to mount an adequate immune response to the COVID-19 vaccine, and
  - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC, or
  - who are at high risk of exposure for those living or working in congregant settings such as a nursing home or prisons

Racial and ethnic minority populations with higher risk of exposure to COVID-19 due to work as an “essential worker” or other social determinants of health, are also encouraged to be considered for prioritized treatment in order to reduce the risk of severe outcomes from COVID-19.

For the full list of eligibility, visit the [NIH COVID-19 Treatment Guidelines](#) site for monoclonal antibodies.



To learn about mAbs therapies against certain COVID-19 variants and find a treatment site for your patients, visit [linktr.ee/healthcareready](https://linktr.ee/healthcareready).

<sup>1</sup> As of 6/24/21 the FDA issued an EUA for tocilizumab (Genentech) for the treatment of COVID-19 in certain hospitalized patients.

## Next Steps

- ✓ **Chat** with your patient if they test positive for COVID-19, or have been exposed to someone with COVID-19.
- ✓ **Assess** if your patient is eligible for mAbs therapy.
- ✓ **Help patients** who qualify find an treatment site nearby through the [National Infusion Center Association Site Locator](https://www.infusioncenter.org): [covid.infusioncenter.org](https://covid.infusioncenter.org).
- ✓ **Explain** to your patient the options for mAbs infusion or subcutaneous injection. For infusion: the therapy is administered through an IV catheter and placed in a patient's arm at the time of infusion. Prior to leaving the infusion center, the IV is removed. The entire process from visit to end can be completed in as little as 45 minutes. Patients will be monitored for one hour after the infusion for any reactions.
- ✓ **Share** [patient testimonials](#) about the benefits of mAbs treatment therapy.



"When I first learned I was a candidate for mAbs, I was excited. To hear that I was going to be ok was amazing. There was no pain, no adverse reaction. That [mAbs] was the reason I did not develop any of the other symptoms, which was a major component of me recovering. So I encourage everyone, if you have that opportunity, take whatever precautions you need to take."

Source: [COVID-19 Monoclonal Antibody Infusion Patient Testimonial- Silvester Stokes](#)

## FAQ

### Where can I find more information on mAbs in general?

Learn more from the HHS site [combatcovid.hhs.gov](https://www.combatcovid.hhs.gov), or the [Infectious Disease Society of America](https://www.idsa.org).

### What are the side effects of mAbs infusion therapy?

Although reactions and side effects are uncommon, some include fever, chills, nausea, dizziness, headache, and rash. Read more about [side effects and adverse reactions](#).

### What are the adverse reactions of mAbs?

Serious and unexpected adverse events including hypersensitivity, anaphylaxis, and infusion-related reactions have been observed.

### What is the latest data on safety and efficacy?

The use of mAbs for COVID-19 treatment is still investigational. Outcomes from ongoing Phase 3 clinical trials are publicly available, and indicate up to 70% risk reduction in COVID-19-related hospitalizations or deaths. Read the Overall Safety Summary for the latest published information on clinical trials: [FDA Fact Sheets on COVID Therapeutics](#).

### What is the cost of mAbs for patients?

The federal government is paying for mAbs manufactured by Eli Lilly and Regeneron. These products are available free of charge to patients, regardless of health insurance and immigration status, and administration is free for [Medicare](#) patients and patients who are [uninsured](#). Providers may need to clarify and confirm any coding/billing requirements with privately insured patients as COVID-19-related treatments and procedures may vary from payer to payer.

### What is the reimbursement for mAbs for providers?

- For [Medicare and Medicaid](#)
- For [uninsured patients](#)

### Can unused Product be returned?

Resources for returning unused product can be found below.

- [Lilly Return Goods Procedure](#)
- [REGEN-COV: Call 844-734-6643](#)