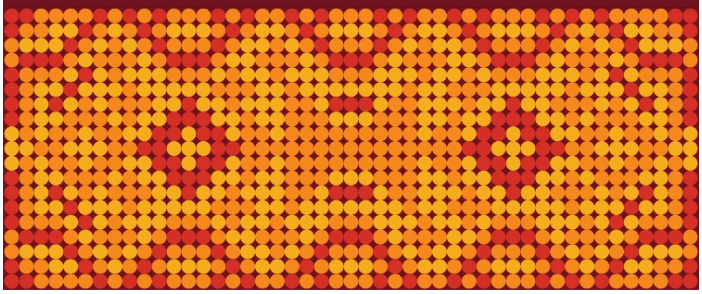
COVID-19 (Coronavirus Disease 2019)

COVID-19 Monoclonal Antibody Treatments



Testing positive for or being exposed to COVID-19 can be an alarming moment, and one of your first questions to yourself or your healthcare provider may be, “Is there anything I can do to avoid getting sick with COVID-19 or sicker if I do have it?”

The good news is that there are currently three new medicines available called monoclonal antibody (mAb) treatments that may reduce your risk of severe COVID-19 symptoms. Depending on your age and medical history, you may qualify for a COVID-19 mAb treatment.

Monoclonal antibody treatments are most effective in the 10 days you first start showing symptoms. It is incredibly important that you contact your health care provider and get tested as soon as possible if you are experiencing COVID-19 symptoms.

What is the difference between antibodies and monoclonal antibodies?

Our immune system naturally makes antibodies to fight off infections. When viruses or other germs infect us, our bodies produce antibodies that target that specific intruder. These antibodies can help destroy the germ or stop it from getting into your cells and making you sicker. Antibodies also help your body remember the germ so in the future your immune system is prepared to attack it if it tries to infect you again.

Monoclonal antibodies are lab-made antibodies that restore, enhance, or mimic the ability of your immune system to fight off germs.[1] Just like the antibodies your immune system makes, monoclonal antibodies target a specific germ and help your body recognize it in the future.

How do COVID-19 mAb treatments work?

The COVID-19 mAb treatments were designed to recognize and attack the virus that causes COVID-19 infection. The COVID-19 mAb treatments block the virus from entering your cells. By blocking entry into your cells, the COVID-19 mAb treatments stop the virus from making you sicker.

What COVID-19 mAb treatments are available now?

Three COVID-19 mAb treatments received Early Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA):[2–4]

- Bamlanivimab and Etesevimab from Eli Lilly and Company
- REGEN-COV from Regeneron Pharmaceutical Inc.
- Strovimab from GlaxoSmithKline LLC

Bamlanivimab and Etesevimab and REGEN-COV are a combination of two mAb treatments mixed together called cocktail treatments: REGEN-COV consists of casirivimab and imdevimab, while the other treatment consists of bamlanivimab and etesevimab. The third mAb treatment contains only one antibody, sotrovimab.

All three COVID-19 mAb treatments are authorized for non-hospitalized patients who have tested positive for COVID-19 in the last 10 days, are 12 years of age and older, weigh at least 88 pounds, and are at high risk of severe COVID-19 and/or hospitalization.[2–4] Bamlanivimab and Etesevimab and REGENCOV have also been authorized for post-exposure prophylaxis (PEP) in **unvaccinated or immunocompromised patients** who meet the previously listed criteria and **have been or will likely be exposed to someone with COVID-19**.[2,3]

How are COVID-19 mAb treatments given?

The three COVID-19 mAbs currently available are administered into your bloodstream in one dose through an intravenous infusion (IV) for at least one hour.[2–4] Treatments given to those exposed to COVID-19 may be administered as a subcutaneous (under the skin) injection.[2,3] Both methods require patients to be monitored for an hour after administration.[2–4] Future treatments may be given differently.

How do I know if I or my child can get a COVID-19 mAb treatment?

Your healthcare provider can help you determine if you or your child may be a candidate for a COVID-19 mAb treatment.

You may be a candidate for treatment if you have a positive COVID-19 PCR test, COVID-19 symptoms starting in the last 10 days, and are[2–4]

65 years of age and older.

55 years of age and older and have

- heart disease,
- high blood pressure, and/or
- COPD/Chronic respiratory disease, including asthma.

Any age and

- are obese (a body mass index [BMI] of 35 or higher),
- have diabetes (Type 1 or Type 2),
- have chronic kidney disease,
- have a weakened immune system, and/or
- you are taking medicine that weakens your immune system.

Your child may be eligible if they are

- 12 to 17 years of age, at least 88 pounds, and
  - are obese (BMI greater than or equal to 85 percent of patients of the same age and gender),
  - regularly use medical technology such as a ventilator or feeding tube,
  - have a developmental condition like cerebral palsy,
  - have sickle cell disease,
  - have congenital or acquired heart disease, and/or
  - have asthma/chronic respiratory problems requiring daily medication for control.

Additionally, you or your child may be eligible to receive a mAb after you've been exposed to COVID-19, meet one or more of the above criteria, are unvaccinated or immunocompromised, and have had close contact with someone who has COVID-19.[2,3]

How were COVID-19 mAb treatments made so quickly?

Researchers were able to create COVID-19 mAb treatments so quickly because mAbs are not a new type of medicine. Researchers have been researching and creating treatments using mAbs for over 30 years.

Monoclonal antibodies were first discovered in 1975. In 1986, the FDA approved the first mAb treatment. As of December 2019, the FDA has approved 79 mAb treatments.[4] Since their discovery, they have become a popular treatment model for various conditions like HIV, influenza, Ebola, the Zika virus, asthma, Crohn's disease, rheumatoid arthritis, and cancer.[5–8]

How are COVID-19 mAb treatments different than COVID-19 vaccines?

COVID-19 mAb treatments give your immune system the antibodies it needs to protect you by stopping the COVID-19 virus from entering your body's cells. They can prevent severe illness if you are already infected with COVID-19. COVID-19 mAb treatments given to you prophylactically after being exposed to COVID-19 may stop the virus from replicating in your body, which prevents you from becoming infected with the SARS-CoV-2 virus.

COVID-19 vaccines train a healthy immune system to protect the body against future diseases. They provide active immunity by exposing your immune system to an imitation version of the COVID-19 virus or one of the specific viral proteins. This triggers your natural immune response and causes you to produce antibodies. Then, if you encountered the COVID-19 virus, you would already have the antibodies that recognize the virus and prevent diseases. With mAbs, the antibodies are given to people directly to help treat the disease immediately.

Find out more information about specific COVID-19 treatments at uihi.org/projects/covid-19-treatment.

You can also learn more about the clinical trials process these authorized COVID-19 treatments go through to ensure they are safe and effective.

References

1. U.S. Food and Drug Administration. COVID-19 Frequently Asked Questions. *FDA*. Published online September 23, 2021. Accessed September 24, 2021. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions
2. U.S. Food and Drug Administration. Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab for Coronavirus Disease 2019 (COVID-19) 09162021. FDA. Published September 16, 2021. Accessed September 24, 2021. https://www.fda.gov/media/145803/download
3. Regeneron Pharmaceuticals Inc. Fact Sheet for Health Care Providers Emergency Use Authorization (EAU) of REGEN-COV (casirivimab and imdevimab). FDA. Published September 2021. Accessed September 23, 2021. https://www.fda.gov/media/145611/download
4. U.S. Food and Drug Administration. Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab. FDA. Published September 10, 2021. Accessed September 24, 2021. https://www.fda.gov/media/149534/download
5. Lu R-M, Hwang Y-C, Liu I-J, et al. Development of therapeutic antibodies for the treatment of diseases. *Journal of Biomedical Science*. 2020;27(1):1. doi:10.1186/s12929-019-0592-z
6. Walker LM, Burton DR. Passive immunotherapy of viral infections: "super-antibodies" enter the fray. *Nat Rev Immunol*. 2018;18(5):297-308. doi:10.1038/nri.2017.148
7. Enlisting Monoclonal Antibodies in the Fight Against COVID-19. NIH Director's Blog. Published May 21, 2020. Accessed September 24, 2021. https://directorsblog.nih.gov/2020/05/21/enlisting-monoclonal-antibodies-in-the-fight-against-covid-19/
8. Monoclonal Antibodies - National Cancer Institute. Published September 24, 2019. Accessed September 24, 2021. https://www.cancer.gov/about-cancer/treatment/types/immunotherapy/monoclonal-antibodies