New Monoclonal Antibody (mAB) Infusion Treatment Available for Recently Diagnosed, High-Risk COVID-19 Outpatients

The FDA recently approved the Emergency Use Authorization for a therapy consisting of monoclonal antibody for the treatment of coronavirus disease 2019 (COVID-19).

Q: What is a monoclonal therapy?

A: Monoclonal antibody therapy is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Monoclonal antibody therapy is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using monoclonal antibodies to treat people with COVID-19.

Q: How do I know if I qualify for monoclonal antibody therapy?

A: Please call your physician or use Virtual Urgent Care. In order to receive this treatment, you must have a physician's referral and a copy of your positive COVID-19 lab result.

Q: Who can receive this medication?

A: Adult, high-risk patients with mild to moderate COVID-19. High risk is defined as patients meeting at least one of the following criteria:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age **AND** have cardiovascular disease, **OR** hypertension, **OR**, chronic obstructive pulmonary disease (COPD)/other chronic respiratory diseases.

Monoclonal antibody therapy should be administered as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset. Patients having started or completed COVID-19 vaccination will be assessed to determine the benefit of monoclonal antibody therapy.

Q: What is an Emergency Use Authorization (EUA)?

A: The United States FDA has made monoclonal antibody infusions available under an emergency access mechanism called an EUA. An EUA means that the drugs have not undergone the same type of review as an FDA-approved product, because the FDA approval process takes a long time. COVID-19 is a national crisis, and we do not have the luxury of the years it takes to go through an FDA approval process. An EUA is a shorter, simpler review process that is not as thorough as the approval process.

To achieve EUA status, monoclonal antibody infusions have given investigators and the FDA reason to believe that the products may be effective in the treatment of COVID-19, and they currently meet the threshold for safety, performance and labeling.

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Q: Are monoclonal antibody infusions such as bamlanivimab and casirivimab/ imdevimab safe and will they work?

A: This medication may help prevent patients from requiring hospitalization, reduce viral load, and minimize symptoms associated with COVID-19. However, there is currently limited evidence as studies remain ongoing. Serious and unexpected results may happen. These drugs are still being studied so it is possible that all of the risks are not known at this time.

Q: I have COVID-19, but I'm not feeling that bad. Should I wait until my symptoms get worse before receiving the monoclonal antibody infusion?

A: It is recommended that you receive treatment as soon as possible. In high-risk patients, receiving treatment earlier when symptoms are less severe may prevent progression of disease that would require hospitalization.

Q: What should I tell my health care provider before I receive COVID-19 monoclonal therapy?

A: Please tell your health care provider about all of your medical conditions, including if you:

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

Q: What if I am pregnant or breastfeeding?

A: There is limited data treating pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving infusions may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your health care provider.

Q: How will I receive the COVID-19 monoclonal antibody therapy?

A: Monoclonal antibody therapy is given to you through a vein (intravenous or IV) for up to 1 hour in an outpatient infusion center. You will receive one dose of monoclonal antibody therapy by IV infusion.

Q: What are the important possible side effects of COVID-19 monoclonal antibody therapy?

A: One possible side effect of monoclonal antibody therapy is an allergic reaction. Allergic reactions can happen during and after infusion with monoclonal antibody therapy such as Bamlanivimab. Tell your health care provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. These are not all the possible side effects of COVID-19 monoclonal antibody therapy. Not a lot of people have been given COVID-19 monoclonal antibody therapy.

Serious and unexpected side effects may happen. COVID-19 monoclonal antibody therapy is still being studied, so it is possible that all of the risks are not known at this time.

Q: How do I report side effects (or medical issues) with infusion therapies?

A: Tell your primary care physician right away if you have any medical issues that bother you or side effects that do not go away.

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Q: What other treatment choices are there?

A: The FDA may allow for the emergency use of other monoclonal antibody therapy like Bamlanivimab, to treat people with COVID-19. Visit **covid19treatmentguidelines.nih.gov** for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your health care provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with COVID-19 monoclonal antibody therapy. Should you decide not to receive the COVID-19 monoclonal antibody therapy or stop it at any time, it will not change your standard medical care.

Q: I'm now feeling much better as a result of the infusion. Can I cut my isolation short and go back to work or resume activities as before?

A: No. Continue to limit exposure to other individuals for 10 days after your symptoms first appeared or at least 24 hours after your symptoms have improved and you've been without fever without using fever-reducing medications. To remain in isolation means staying in your home, washing your hands, disinfecting commonly-shared hard surfaces, and staying at least 6-feet apart from others. You can return to work after you have met all of the requirements to end isolation.

Q: I feel better but my employer wants me to get a new COVID-19 test before coming back to work. Should I be retested?

A: It probably will not help you to be retested at this time. Studies show that many people who test positive will continue to test positive for up to three months. You should continue to limit exposure to other individuals for 10 days after your symptoms first appeared or least 24 hours after your symptoms have improved and you've been without fever without using fever-reducing medications, after which you can return to work.

Q: Can I receive the COVID-19 vaccine after having a monoclonal antibody infusion?

A: It is recommended that patients wait 90 days after receiving a COVID-19 monoclonal antibody treatment before taking the COVID-19 vaccine.

Q: How can I learn more?

- Ask your health care provider
- Visit **covid19treatmentguidelines.nih.gov**
- Contact your local or state public health department

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