

**Fact Sheet for Patients, Parents and Caregivers\***  
**Emergency Use Authorization (EUA) of Monoclonal Antibody Treatment for Coronavirus Disease (COVID-19)**

You are being offered a treatment called monoclonal antibody for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking monoclonal antibody treatment.

Receiving monoclonal antibody treatment may benefit certain people with COVID-19. Read this Fact Sheet for information about monoclonal antibody treatment. Talk to your healthcare provider if you have questions. It is your choice to receive monoclonal antibody treatment or stop it at any time.

**What is monoclonal antibody treatment?**

Monoclonal antibody treatment is an investigational therapy used to treat mild to moderate symptoms of COVID-19 in non-hospitalized adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)), and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization.

Monoclonal antibody treatment is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using monoclonal antibody treatment to treat people with COVID-19.

The FDA has authorized the emergency use of monoclonal antibody treatment for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section “**What is an Emergency Use Authorization (EUA)?**” at the end of this Fact Sheet.

**What is the actual medicine name?**

There are several monoclonal antibody treatments available to treat COVID-19, including “casirivimab/imdevimab (CASIM)”, “bamlanivimab/etesivimab (BAM-ETE)”, and others. Your doctors will select the therapy that is available and that is most effective against the COVID-19 virus. You will be given more detailed information about the specific medication at the time that you receive treatment.

**What should I tell my healthcare provider before I receive monoclonal antibody treatment?**

Tell your healthcare 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)

### **How will I receive monoclonal antibody treatment?**

- Monoclonal antibody treatment is given to you through a vein (intravenous or IV).
- You will receive one dose of monoclonal antibody treatment by IV infusion. The infusion will take 16 – 60 minutes or longer. Your healthcare provider will determine the duration of your infusion.

### **What are the important possible side effects of monoclonal antibody treatment?**

Possible side effects of monoclonal antibody treatment are:

- **Allergic reactions.** Allergic reactions can happen during and after infusion with monoclonal antibody treatment. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness, and sweating. These reactions may be severe or life threatening.
- **Worsening symptoms after monoclonal antibody treatment:** You may experience new or worsening symptoms after infusion, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to monoclonal antibody treatment infusion or are due to the progression of COVID-19.

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 monoclonal antibody treatment. Not a lot of people have been given monoclonal antibody treatment. Serious and unexpected side effects may happen. Monoclonal antibody treatment is still being studied so it is possible that all of the risks are not known at this time. It is possible that monoclonal antibody treatment could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, monoclonal antibody treatment may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

### **What other treatment choices are there?**

Like monoclonal antibody treatment, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.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 healthcare provider may talk with you about clinical trials you may be eligible for. It is your choice to be treated or not to be treated with monoclonal antibody treatment. Should you decide not to receive monoclonal antibody treatment or stop it at any time, it will not change your standard medical care.

**What if I am pregnant or breastfeeding?**

There is limited experience treating pregnant women or breastfeeding mothers with monoclonal antibody treatment. For a mother and unborn baby, the benefit of receiving monoclonal antibody treatment may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

**How do I report side effects with monoclonal antibody treatment?**

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to FDA MedWatch at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), call 1-800-FDA-1088.

**How can I learn more?**

- Ask your healthcare provider
- Visit <https://www.covid19treatmentguidelines.nih.gov/>
- Contact your local or state public health department

**What is an Emergency Use Authorization (EUA)?**

The United States FDA has made monoclonal antibody treatment available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Monoclonal antibody treatment has not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for monoclonal antibody treatment is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the product may no longer be used).