Frequently asked questions about Monoclonal Antibody Infusion Treatment

What are monoclonal antibodies for COVID-19?
Monoclonal antibodies for COVID-19 are investigational medicines used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older. Bamlanivimab and casirivimab + imdevimab were recently approved by the FDA and are the first of what is likely to be multiple outpatient, non-vaccine treatments. These antibodies are investigational because they are still being studied. There is limited information known about the safety or effectiveness of using these medicines to treat people with COVID-19. The FDA has authorized the emergency use of monoclonal antibodies for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information, see “What is an Emergency Use Authorization” at the end of this fact sheet.

Who is this treatment for?
This infusion treatment option is for people with COVID-19 who:
• Are 12 years of age or older and weigh at least 88 pounds
• Have mild to moderate symptoms for 7 days or less
• Are at high risk to get very sick from COVID-19

Monoclonal antibody infusion is not for people who are already in the hospital because of their COVID-19 symptoms.

Am I at high risk?
For adults, monoclonal antibody infusion may be an option if you:
• Are age 65 or older
• Have obesity, with a body mass index (BMI) of 35 or higher
• Have diabetes, chronic kidney disease, or a condition that weakens the immune system, or take a medication that weakens the immune system
• Are age 55 or older and have heart disease, high blood pressure or lung disease

For pediatric patients age 12-17, monoclonal antibodies may be an option if you:
• Have obesity, with a BMI higher than 85 percent of patients your same age and gender
• Have heart disease, sickle cell disease, or long-term lung disease
• Have a developmental condition like cerebral palsy
• Regularly use medical technology, like a ventilator or feeding tube

How do these medicines work?
Monoclonal antibodies are viral neutralizing medicines. This means they may contain man-made antibodies that are similar to the antibodies of patients who have recovered from COVID-19. These antibodies may help limit the amount of COVID-19 virus in your body, which could give your body more time to learn how to make its own antibodies.

How will I take the medicine?
Monoclonal antibodies are given to you through a vein (intravenous or IV) for at least one hour. You will receive one dose of this medicine. After the infusion, you will need to stay for one more hour to make sure you are feeling okay to go home.
What are the side effects?
Side effects can range from mild to serious and may include:

- Wheezing or trouble breathing
- Swollen lips, face or throat
- Flu-like symptoms (fever, sweating, chills, cough, sore throat, headache or muscle pain)
- Upset stomach (nausea, vomiting or diarrhea)
- Itching, swelling, rash or hives
- Dizziness or low blood pressure
- Changes in your heartbeat

Tell your doctor or nurse right away if you have any side effects during or after your infusion.

Keep in mind that only a limited number of people have taken COVID-19 monoclonal antibody treatment – scientists are still learning about its side effects and risks. Serious and unexpected side effects may occur.

What if I am pregnant or breast feeding?
Monoclonal antibodies have not been used on many pregnant or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving this medicine may be greater than the risk from treatment. If you are pregnant or breastfeeding, discuss with your health care provider.

How can I get ready for my appointment?
Plan for the infusion appointment to take about 3-4 hours. Most people will go home the same day, unless they have a serious side effect from the infusion.

Before the appointment, make sure to get good night’s sleep, drink plenty of water, and eat a light meal. Wear warm, comfortable clothes, including a shirt with sleeves you can roll up over your elbows. It’s also important to wear a mask to prevent the spread of COVID-19.

When the clinic calls to make your appointment, you will be told where to go and what precautions you will take to prevent the spread of COVID-19.

What happens after my appointment?
Tell your health care provider right away if you have side effects or new symptoms that bother you or don’t go away.

If you have any side effects, you may report these to FDA MedWatch at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

What is an Emergency Use Authorization (EUA)?
The United States FDA has made these medications available under an emergency access mechanism called an Emergency Use Authorization (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.

These medications have 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 include 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 antibodies 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).

How can I learn more?
Visit MercyOne.org or www.covid19treatmentguidelines.nih.gov. You may also contact your health care provider for more information.