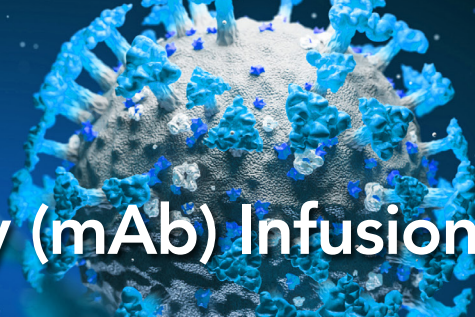


COVID - 19

Monoclonal Antibody (mAb) Infusions FAQ



CLINIC HOURS ARE: Monday - Friday 8:00a.m. - 5:00p.m.
Closed on weekends.

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

- Food and Drug Administration (FDA) authorization of an unapproved product or unapproved uses of an approved product for emergency use.
- Emergency use authorization is NOT the same as FDA approval or licensure.
- EUA is still considered an investigational state.

Q. Casirivimab + Imdevimab are monoclonal antibodies, what does that mean?

- Monoclonal antibodies are molecules produced in a laboratory to mimic the immune system's ability to provide a response.
- Casirivimab + Imdevimab neutralize and binds to receptors on the virus decreasing its ability to infect the patient.

Q. Is Casirivimab + Imdevimab FDA approved?

- No, these monoclonal antibody treatments have been granted an EUA for the treatment of mild to moderate COVID-19 in adults and pediatric patients who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- They are still considered investigational treatments.

Q. I tested positive for COVID-19, do I need this drug?

- Patients must first have a COVID-19 positive test with mild to moderate symptoms of COVID-19.
- Patients need to be at high risk of progressing to severe COVID-19 disease or hospitalization.
- Patients must have one of the following criteria:
 - ◆ Body mass index (BMI) ≥ 25
 - ◆ Chronic kidney disease
 - ◆ Diabetes
 - ◆ Immunosuppressive disease
 - ◆ Currently receiving immunosuppressive treatment
 - ◆ ≥ 65 years of age
 - ◆ Cardiovascular disease (including Congenital Heart Disease)
 - ◆ Hypertension
 - ◆ Chronic lung diseases (chronic obstructive pulmonary disease/other chronic respiratory disease)
 - ◆ Neurodevelopmental disorders
 - ◆ Sickle Cell Disease
 - ◆ Having a medical-related technological dependence (ex. a tracheotomy, positive pressure ventilation)

Q. If I meet the criteria, how soon should I receive this drug?

- As soon as possible but within 10 days of COVID-19 symptoms.

Q. If I get admitted to the hospital can I receive this drug?

- No, this drug cannot be administered to patients that are hospitalized .

Q. Are there other reasons I cannot receive this drug?

- If you need oxygen therapy due to COVID-19.
- If you have chronic oxygen needs and require an increase in baseline oxygen flow rate due to COVID-19.

Q. Do these drugs have side effects?

- Monoclonal antibody drugs can cause allergic reactions, such as anaphylaxis and infusion-related reactions.
- In the Casiribimab + Imdevimab trials reactions included pneumonia, hyperglycemia, nausea, vomiting, and infusion-related reactions. There was one reported anaphylactic reaction which was resolved with drug therapy.

Q. How long is the infusion?

- The infusion is given over 60 minutes, after which you will be observed for reactions for one hour.

Q. What happens if I get a reaction after I go home?

- After you receive the infusion you will receive a handout with instructions on what do after you leave, and any reaction occurs.

Q. Is there a cost for Casiribimab +Imdevimab?

- There is no cost to the patient for the drug.
- Infusion time and supplies will be billed to the patient's insurance.

Q. If I receive Casiribimab + Imdevimab, does this mean I won't get hospitalized?

- It is still possible that your symptoms could progress; please follow the recommendations provided to you by your provider .
- It is important to continue following federal and state guidelines on quarantining as COVID-19 positive and wearing a mask, social distancing and washing your hands.

Q. How is Lovelace Health System providing the drug?

- Lovelace Health System is accepting outside referrals for those who meet the criteria.
- Lovelace Health System is not taking walk in appointments.

Q. If I still have questions, who can I talk to?

- Please speak with your healthcare provider to get further information.