

# COVID - 19

## Monoclonal Antibody (MAb) Infusions FAQ



### 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. Bamlanivimab and 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
- Bamlanivimab is designed to block the virus from attaching to human cells and therefore stopping it from causing further infection
- Casirivimab + Imdevimab neutralize and binds to receptors on the virus decreasing its ability to infect patients

### Q. Are Bamlanivimab or 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. Is one treatment better than another?

- There is no data to show that one EUA COVID-19 monoclonal antibody is better than the other
- Both treatments are intravenous infusions and Casirivimab + Imdevimab are given together in one infusion.

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

- Patients must first have a COVID-19 positive test
- 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)  $\geq 35$
  - ◆ Chronic kidney disease
  - ◆ Diabetes
  - ◆ Immunosuppressive disease
  - ◆ Currently receiving immunosuppressive treatment
  - ◆  $\geq 65$  years of age
  - ◆  $\geq 55$  years of age AND have
    - Cardiovascular disease or
    - Hypertension or
    - Chronic obstructive pulmonary disease/other chronic respiratory disease

### 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?**

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

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

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- 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?**

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- Monoclonal antibody drugs can cause allergic reactions, such as anaphylaxis and infusion-related reactions
- In the Bamlanivimab BLAZE-1 trial there were no serious infusion-related reactions reported. The most common Bamlanivimab reactions were nausea, diarrhea, dizziness, headache, itching and vomiting. If you receive these treatments, you will be monitored during and for a minimum of 1- hour following the infusion for adverse events
- 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?**

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- 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?**

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- 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 Bamlanivimab or Casiribimab +Imdevimab?**

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- 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 Bamlanivimab or Casiribimab + Imdevimab, does this mean I won't get hospitalized?**

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- 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?**

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- Lovelace Health System will be identifying eligible patients through specific providers caring for COVID patients
- Lovelace Health System is not taking walk-in appointments or outside clinic referrals at this time

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

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- Please speak with your healthcare provider to get further information