COVID-19 Vaccination – UPDATES –

MAB Treatments 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) ≥35
    - Chronic kidney disease
    - Diabetes
    - Immunosuppressive disease
    - Currently receiving immunosuppressive treatment
    - ≥65 years of age
    - ≥55 years of age AND have
        - Cardiovascular disease or
        - Hypertension or

        - Chronic obstructive pulmonary disease/other chronic respiratory disease
    - 12 – 17 years of age AND have
        - BMI ≥85th percentile for their age and gender based on CDC growth charts or
        - Sickle cell disease or
        - Congenital or acquired heart disease or
        - Neuro-developmental disorders, for example, cerebral palsy or
        - A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19) or
        - Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

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 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?

- 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?

- Directions will be provided for a follow-up and contact information at the completion of the infusion

Q. Is there a cost for Bamlanivimab or Casiribimab + Imdevimab?

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

Updated: January 20, 2021

Q. Will Medicare cover these drug therapies?

- Monoclonal antibody products to treat COVID-19 will initially be given to health care providers at no charge. Medicare will not pay for the monoclonal antibody products to treat COVID-19 that health care providers receive for free but will provide payment for the infusion (that is, administration) of the product during the COVID-19 Public Health Emergency, when furnished consistent with the Emergency Use Authorization.
- When health care providers begin to purchase these monoclonal antibody products, CMS anticipates setting the Medicare payment rate in the same way it anticipates setting the payment rates for other COVID-19 vaccines when administered in the hospital inpatient setting, which is based on reasonable cost

Q. If I receive Bamlanivimab or 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 Hillcrest HealthCare System providing the drug?

- Hillcrest HealthCare System provides these services through the outpatient clinics with direct referrals from Utica Park Clinic, Oklahoma Heart Institute or any one of our hospital emergency departments. The services are dependent on the availability of the MAB infusions. We cannot take walk-ins or outside referrals.

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

- Please speak with your healthcare provider to get further information

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