

1/5/2020

**UNDER NO CIRCUMSTANCES SHOULD ONE CALL THE HATZALAH EMERGENCY DISPATCH LINE REGARDING THIS THERAPY**

### **What is Monoclonal Antibody Therapy?**

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as viruses. Bamlanivimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.

### **What is Bamlanivimab?**

Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Bamlanivimab is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab to treat people with COVID-19.

The FDA has authorized the emergency use of bamlanivimab 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.

### **Who is eligible for this treatment?**

- You must have tested positive for COVID19 (PCR or rapid)
- Your physician must submit a referral.
- You must be considered "high risk" by the EUA. See list here

### **Is there a maximum time frame for one to receive this therapy?**

The EUA only allows this therapy to be given within 10 days of symptom onset.

### **Why can't I sign myself up for this therapy?**

The FDA EUA requires a physician to refer the therapy

### **My physician would like me to get the therapy but does not know how to sign up. What should I do?**

Have your doctor contact us at [covidtherapy@hatzalahbaltimore.org](mailto:covidtherapy@hatzalahbaltimore.org) and we will give them access to the online referral form.

### **Can this therapy be obtained at any Dr office or Hospital?**

No, only authorized providers can provide this therapy.

### **Is there an out of pocket expense for this therapy?**

No, your insurance will be billed for this therapy. There is no co-pay, and no out of pocket pay.

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**How long does the Infusion take?**

The infusion will take approximately 1 hour and there is another hour observation period following the infusion. Expect to be there for three hours.

**Can I eat and drink during the infusion?**

We ask that people receiving the infusion not eat or drink, and keep their mask on at all times, for the safety of the staff.

**What should I tell my healthcare provider before I receive bamlanivimab?**

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 bamlanivimab?**

Bamlanivimab is given to you through a vein (intravenous or IV) for at least 1 hour.

You will receive one dose of bamlanivimab by IV infusion.

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

The United States FDA has made bamlanivimab 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. Bamlanivimab 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 bamlanivimab 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).

**Can I still get the vaccine after I receive bamlanivimab?**

Yes, you can still get the vaccine. However, according to the FDA, one should wait 90 days from the day the received bamlanivimab to get the vaccine. If you have already received the first vaccine, and got COVID in between the first and second vaccines, you should wait 90 days before getting the second vaccine.