COFFEE REGIONAL MEDICAL CENTER

# Bamlanivimab Protocol Orders
## (FOR OUTPATIENT IV INFUSION USE ONLY)

3PO

1. **FDA Emergency Use Authorization (EUA) for the treatment of mild to moderate COVID−19**
**All Inclusion criteria listed below must be met (check when verified) :**

❑ Confirmation of COVID−19 via positive PCR or antigen test

❑ Treatment within 10 days of symptom onset  Date of symptom onset: _____

❑ Patient symptomatic but not yet progressed to require hospitalization or oxygen therapy.

❑ High−risk adult or pediatric patient 12 years and older > 40 kg. High −risk defined by a combination of risk factors such as:

**High risk is defined as patients who meet at least one of the following criteria.**

- Have a body mass index (BMI) 35 or greater
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive treatment
- Are 65 years of age or older

**Are 55 years of age AND have**

- Cardiovascular disease, OR
- Hypertension, OR
- Chronic Obstructive Pulmonary Disease/other Chronic Respiratory disease

**Are 12 −17 years of age AND have**

- BMI 85% for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm OR
- Sickle cell disease, OR
- Congenital or acquired heart disease, OR
- Neurodevelopment disorders, for example; cerebral palsy OR
- Medical−related technological dependance, for example; tracheostomy, gastrostomy, positive pressure ventilation(not related to COVID−19) OR
- Asthma, reactive airway, other chronic respiratory disease that requires daily medication for control.

❑ Adult or pediatric patient who **IS NOT** hospitalized due to COVID−19, ***AND***
Adult or pediatric patient who **DOES NOT** require oxygen therapy due to COVID−19, ***OR***

❑ Adults or pediatric patient who **DOES NOT** require an increase in baseline oxygen flow rate due to COVID−19 in those patients on chronic oxygen therapy due to underlying non−COVID−19−related comorbidity.

2. **IV Infusion Therapy:**

- Peripheral IV − start Normal Saline at KVO.
- Notify Pharmacy when IV access is established.
- No pre−medications necessary. Follow OP IV Therapy Infusion Reaction Protocol in the event of patient adverse reaction to medication.



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2. **IV Infusion Therapy: Cont.**

- Vital Signs pre−infusion, 15 minutes after start of infusion, then every 30 minutes during, and one hour after completion of dose.
- A nurse to be in attendance during the first 15 minutes of infusion, and then close observation for the remainder of infusion.
- If patient develops flushing of face, chest tightness, chills, fever, dizziness, nausea, diaphoresis, or hypotension, stop infusion and restart normal saline. Take vital signs and notify physician and pharmacist. Monitor until condition resolves.
- Have immediately available, T B syringe, 12ml syringe, 22 gauge needles x2, Epinephrine 1:1000 x1 amp, sterile water x2, Benadryl 50mg inject x1 amp, and 3ml syringe.

3. **Patient Consent and Education Prior to Medication Administration:**

- Follow procedure for obtaining patient consent using the "**Alternative Consent Form**" for use when procedure specific form is not available. (Located in the Access Repository)
- You must communicate to the patient information consistent with the "Fact Sheet for Patients and Parents/Caregivers for the Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID−19)" and provide a copy of the Fact Sheet) prior to the patient receiving Bamlanivimab *(see attached).*

4. **Dose and Administration Instructions:**

- **Bamlanivimab 700mg in 200ml Normal Saline via IV infusion over at least 60 minutes X 1 dose**.
- Administer via pump using a polyvinylchloride (PVC) of polyethersulfone (PES) set containing a 0.22 micron in−line filter.
- Flush line with normal saline after infusion complete to insure delivery of the total dose.
- Observe patient for at least 1 hour after infusion is complete.

5. **Patient Discharge Instructions:**

- Provide patient a copy of the **EUA Bamlanivimab Fact Sheet**
- Instruct patient to continue to self−isolate and use infection control measures (e.g. wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

| Physician Signature | Date | Time |
|---|---|---|



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You are being given a medicine called **bamlanivimab** for the treatment of Coronavirus disease 2019 (COVID−19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab, which you may receive.

Receiving bamlanivimab may benefit certain people with COVID−19.

Read this Fact Sheet for information about bamlanivimab. Talk to your healthcare provider if you have questions. It is your choice to receive bamlanivimab or stop it at any time.

**What is COVID−19?**
COVID−19 is caused by a virus called a Coronavirus. People can get COVID−19 through contact with another person who has the virus.

COVID−19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID−19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long−lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID−19.

**What are the symptoms of COVID−19?**
The symptoms of COVID−19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

**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.

**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 are the important possible side effects of bamlanivimab?**
Possible side effects of bamlanivimab are:
• Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied so it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab could interfere with your body's own ability to fight off a future infection of SARS−CoV−2. Similarly, bamlanivimab may reduce your body's immune response to a vaccine for SARS−CoV−2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

**What other treatment choices are there?**
Like bamlanivimab, FDA may allow for the emergency use of other medicines to treat people with COVID−19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID−19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with bamlanivimab. Should you decide not to receive bamlanivimab or stop it at any time, it will not change your standard medical care.

**What if I am pregnant or breastfeeding?**
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab. For a mother and unborn baby, the benefit of receiving bamlanivimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

**How do I report side effects with bamlanivimab?**
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, call 1−800−FDA−1088, or contact Eli Lilly and Company at 1−855−LillyC19 (1−855−545−5921).

**How can I learn more?**
• Ask your healthcare provider
• Visit www.bamlanivimab.com
• Visit https://www.covid19treatmentguidelines.nih.gov/
• Contact your local or state public health department

**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).

Literature issued November 2020





New 11/30/2020

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# ALTERNATIVE CONSENT FORM

**(ALTERNATIVE FORM FOR USE WHEN PROCEDURE SPECIFIC FORM IS NOT AVAILABLE)**

3CNT

## REQUEST AND INFORMED CONSENT TO (PROCEDURE OR DIAGNOSTIC TEST)

***DO NOT SIGN THIS FORM UNTIL YOU HAVE READ IT AND FULLY UNDERSTAND ITS CONTENT***

The following has been explained to me in general terms and I understand that:

1) The diagnosis requiring this procedure is: _____

_____

*(diagnosis described in layman's terms)*

2) The nature of this procedure is: _____

*(describe procedure in layman's terms)*

3) The purpose of this procedure is: _____

*(specific for this patient)*

4) **MATERIAL RISKS OF THIS PROCEDURE:**

As a result of this procedure being performed, there may be material risks of: **INFECTION, ALLERGIC REACTION, DISFIGURING SCAR, SEVERE LOSS OF BLOOD, LOSS OR LOSS OF FUNCTION OF ANY LIMB OR ORGAN, PARALYSIS, PARAPLEGIA, OR QUADRIPLEGIA, BRAIN DAMAGE, CARDIAC ARREST OR DEATH.**

5) In addition to these material risks, there may be other possible risks involved in this procedure including but not limited to: _____

_____

6) The likelihood of success of the above procedure is: ☐ Good ☐ Fair ☐ Poor

7) Practical alternatives to this procedure include: _____

_____

8) If I choose not to have the above procedure, my prognosis (future medical condition) is: _____

_____

_____

*(to be filled out during informed consent process)*

I understand that the physician, medical personnel and other assistants will rely on statements about the patient, the patient's medical history and other information in determining whether to perform the procedure or the course of treatment for the patient's condition and in recommending the procedure which has been explained.

I understand that the practice of medicine is not an exact science and that NO GUARANTEES OR ASSURANCES HAVE BEEN MADE TO ME concerning the results of this procedure.

I understand that during the course of the procedure described above, it may be necessary or appropriate to perform additional procedures which are unforeseen or not known to be needed at the time this consent is given. I consent to and authorize the persons described herein to make the decisions concerning such additional procedures. I also consent to and authorize the performance of such procedures as they deem necessary or appropriate.

**I acknowledge that some or all of the health care professionals performing services in this hospital are independent contractors and are not hospital agents or employees. Independent contractors are responsible for their own actions and the hospital shall not be liable for the acts or omissions of any such independent contractors.**

I also consent to diagnostic studies, tests, anesthesia, x−ray examinations and any other treatment or courses of treatment relating to the diagnosis or procedures described herein.

I also consent that any tissues, specimens, organs or limbs removed from the patient's body in the course of any procedure may be tested or retained for scientific or teaching purposes and then disposed of within the discretion of the physician, facility or other health care provider.

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# ALTERNATIVE CONSENT FORM

**(ALTERNATIVE FORM FOR USE WHEN PROCEDURE SPECIFIC FORM IS NOT AVAILABLE)**

BY SIGNING THIS FORM, I ACKNOWLEDGE THAT I HAVE READ OR HAD THIS FORM READ AND/OR EXPLAINED TO ME; THAT I FULLY UNDERSTAND ITS CONTENT; THAT I HAVE BEEN GIVEN AMPLE OPPORTUNITY TO ASK QUESTIONS AND THAT ANY QUESTIONS HAVE BEEN ANSWERED SATISFACTORILY. ALL BLANK'S OR STATEMENTS REQUIRING COMPLETION WERE FILLED IN AND ALL STATEMENTS I DO NOT APPROVE OF WERE STRICKEN BEFORE I SIGNED THIS FORM. I ALSO HAVE RECEIVED ADDITIONAL INFORMATION INCLUDING BUT NOT LIMITED TO THE MATERIALS LISTED BELOW, RELATED TO THE PROCEDURES DESCRIBED HEREIN.

I hereby voluntarily consent to all Dr. _____ or any physician designated or selected by him or her and all Medical personnel under the direct supervision and control of such physician and all other personnel who may otherwise be involved in performing such Procedures to perform the procedures described or otherwise referred to herein.

_____ _____

Witness | Person Giving Consent

_____ _____ _____ _____

Date | Time | Date | Time

_____ _____

Physician's Signature | Relationship to Patient if not the Patient

_____ _____

Date | Time

Patient unable to sign because of _____

_____

Additional materials used, if any, during the informed consent process for this procedure include: _____

_____

_____