BalladHealth
It's your story. We're listening.

Monoclonal Antibody
Provider Verification and Patient Consent to Treatment

Patient Name: _____ Account #: _____

Primary Care Provider: _____ Referred by: _____

Provider Verification:

I have evaluated the patient identified herein and reviewed the lab results provided. This patient has at least one Risk factor, documented Positive PCR or Antigen test for Covid-19, and Negative antibody test for Covid 19.

Antibody positive or negative _____ Date _____ **Allergies:** _____

(If more than one calendar day, repeat)

PCR positive or negative _____ Date_____ _____

Antigen positive or negative_____Date_____ _____

Risk Factors – Please check all that apply (these are straight from the FDA EUA)

	All patients 18 years of age or older who meet at least 1 of the following
	Age ≥ 65 years of age
	BMI ≥ 35
	Chronic kidney disease
	Diabetes
	Immunosuppressive disease
	Receiving immunosuppressive treatment

	Patients ≥ 55 years of age AND have any of the following
	Cardiovascular disease
	Hypertension
	COPD or other chronic respiratory disease

☐ Based on these findings the patient **IS** a candidate for Monoclonal Antibody Therapy.
☐ Based on these findings the patient **IS NOT** a candidate for Monoclonal Antibody Therapy.

Preferred Outpatient Infusion Center: _____

_____ _____

Signature of provider Date and time

Consent for Treatment

I have been educated on the indications, potential risks and benefits of Monoclonal Antibody therapy for COVID-19.
I have had the opportunity to ask questions related to this therapy and I consent to treatment with Monoclonal Antibody.

_____ _____

Printed name of patient or legal guardian if minor Date/Time

_____

Patient signature or signature of legal guardian if minor

Patient Label Here

Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19)

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.

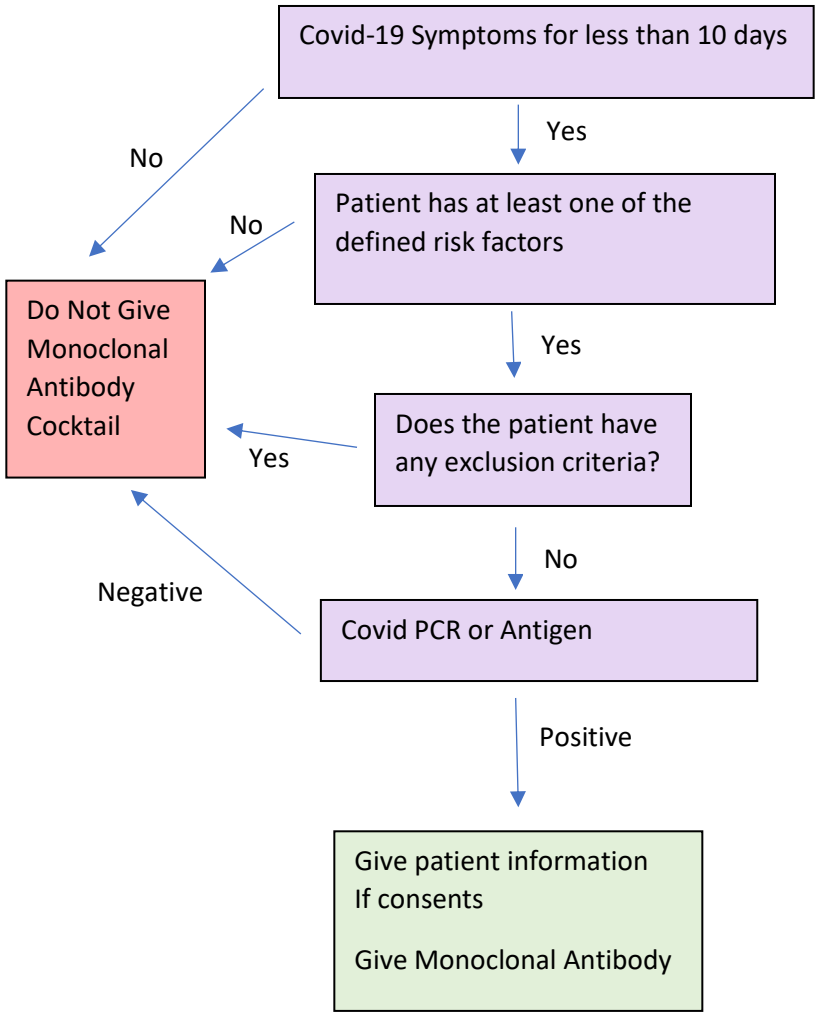
The EUA for bamlanivimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the product may no longer be used).

Literature issued November 2020

Eli Lilly and Company, Indianapolis, IN 46285, USA

5.0-BAM-0000-EUA PAT-20201109

Monoclonal Antibody Algorithm



Exclusion:
Hospitalization
Oxygen use or Increase use of oxygen due to Covid
weight < 40 kg, 88 lbs

(These are straight from the FDA EUA)

Risk factors:
- BMI ≥35
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease
- Receiving immunosuppressive treatment
- Age ≥ 65 years

Additional Risk Factors:

- Age ≥ 55 years AND have any of the following
    - Cardiovascular disease
    - Hypertension
    - COPD/other chronic respiratory disease

Adolescents (Age 12-17 years) who meet at least 1 of the following criteria:
- BMI ≥85th percentile for age/gender
- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental disorders (e.g. cerebral palsy)
- Medical-related technological dependence [e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)]
- Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

OUTPATIENT COVID-19 MONOCLONAL ANTIBODY ORDERS - ADULT

BalladHealth

Form: 3040007057

CEOC APPROVED:12/10/2020

Patient Identification

THIS ORDER SET IS ONLY FOR THE USE FOR NON-HOSPITALIZED PATIENTS WHO ARE POSITIVE FOR COVID-19

- ■ Place patient into COVID-19 designated bed / room
- ■ Enhanced Droplet plus Eye Protection Precautions.

❑ Confirmed direct SARS-CoV-2 (COVID-19) viral test **within three days of test results and 10 days of symptom onset AND**

- **Mild to moderate symptoms**
- **Weighing at least 40 kg**
- **At high risk for progressing to severe COVID-19 and / or hospitalization**

■ **CRITERIA for HIGH RISK** is defined as patients who meet **at least one** of the following criteria:

- ❑ Have a body mass index (BMI) greater or equal to 35
- ❑ Have chronic kidney disease
- ❑ Have diabetes
- ❑ Have immunosuppressive disease
- ❑ Are currently receiving immunosuppressive treatment
- ❑ Are greater or equal to 65 years of age
- ❑ Are greater or equal to 55 years of age **AND** have cardiovascular disease
- ❑ Are greater or equal to 55 years of age **AND** have hypertension
- ❑ Are greater or equal to 55 years of age **AND** have chronic obstructive pulmonary disease/other chronic Respiratory disease.

WEB BASED REFERENCES:

CDC growth charts: https://www.cdc.gov/growthcharts/clinical_charts.htm
Bamlanivimab EUA Approval: https://www.fda.gov/media/143602/download
Bamlanivimab Health Providers EUA Fact Sheet: https://www.fda.gov/media/143603/download
Bamlanivimab Patient and Caregivers EUA Fact Sheet: https://www.fda.gov/media/143604/download
Casirivimab and imdevimab EUA Approval: https://www.fda.gov/media/143891/download
Casirivimab and imdevimab Health Providers EUA Fact Sheet:
https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf
Casirivimab and imdevimab Patient and Caregivers EUA Fact Sheet: https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-patient.pdf

■ **COVID-19 ISOLATION ORDERS:**

- ■ **Communication:** Immediately place patient in Standard, Contact, and Enhanced Droplet plus Eye protection precautions.
- ■ **Notify**: Facility Nursing Supervisor for Standard Contact, Enhanced Droplet plus Eye protection precautions
- ■ Standard Precautions
- ■ Enhanced Droplet plus Eye Protection Precautions.
- ■ Place patient into COVID-19 designated bed / room

CODE STATUS:

■ **CODE STATUS:** ❑ Full Code ❑ No Code / DNR ❑ Do Not Intubate ❑ Other: _____

Best Practice References Advise:

■ **AVOID:** Both bamlanivimab and the combination of casirivimab and imdevimab are NOT to be used for HOSPITALIZED Patients or in those requiring oxygen therapy due to COVID-19

■ Clinically monitor patients during infusion and observe for at least 1 hour after infusion is complete.

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Form: 3040007057

CEOC Date: 12/10/2020

Patient Identification

Signs and symptoms of infusion related reactions may include: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.
If an infusion-related reaction occurs, consider slowing or stopping the infusion and administering appropriate Medications and / or supportive care.

MEDICATIONS:

❑ acetaminophen (Tylenol) 650 mg PO every 4 hours PRN for MILD PAIN (Pain Scale 1 to 3) or for temperature greater than 101 degrees Fahrenheit. If unable to take PO, change route to rectal suppository 650 mg.
***Note: The total daily dose of acetaminophen from all medications should not exceed 4,000 mg per day**

❑ diphenhydrAMINE (Benadryl) 25 mg PO every 4 hours PRN for infusion related reactions and / or nausea

❑ albuterol (Proventil / Accuneb) 0.083% nebulizer solution, 25 mg, every 20 minutes PRN, Nebulization, bronchospasm X 2 doses. Second dose may be repeated in 20 minutes if needed.

❑ ondansetron (Zofran-ODT) disintegrating tablet 4 mg every 1 hour PRN, oral, nausea, vomiting X 2 Doses.
A second dose may be repeated in one hour if nausea persists.

BASED ON AVAILABILITY PHARMACIST MAY INTERCHANGE BELOW THERAPEUTICS.

■ (MS-7742) Informed Consent for Monoclonal Antibody (MAB) Treatment

❍ bamlanivimab

MD to attest to that Emergency Use Authorization (EUA) form has been received by BOTH MD and patient

EXCLUSIONS:

- Patients hospitalized due to COVID-19
- Patients who require oxygen therapy due to COVID-19
- Patients on chronic oxygen therapy that require an increase in baseline oxygen flow rate due to COVID-19
- NOTE: Extreme limited availability

INCLUSION:

- Outpatient with confirmed positive SARS-CoV-2 PCR within three days of test results.
- 10 days or less since symptom onset
- Weighing at least 40 kg
- At high risk for progressing to severe COVID-19 and / or hospitalization

■ bamlanivimab 700 mg IV infusion over 60 minutes ONCE on Day 1
■ Flush line with sodium chloride 0.9% to ensure delivery of entire dose.

■ Bamlanivimab EUA Fact Sheet – Give to Patient
■ Bamlanivimab EAU Fact Sheet for Health Care Providers

❍ casirivimab and imdevimab
■ casirivimab 1200 mg and imdevimab 1200 mg over 60 minutes ONCE on Day 1
■ Flush line with sodium chloride 0.9% to ensure delivery of entire dose.

■ Casirivimab and Imdevimab EAU Fact Sheet for Health Care Providers

Informed Consent for Monoclonal Antibody (MAB) Treatment

Patient Identification

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Your physician has recommended that you consider receiving monoclonal antibody treatment for COVID-19. This treatment will be either with bamlanivimab or casirivimab / imdevimab. ***YOU HAVE THE RIGHT TO ACCEPT OR DECLINE THE RECOMMENDED TREATMENT.*** We have provided you one or more fact sheets and recommend that you read those fact sheets, and ask additional questions of your healthcare provider if additional clarification is needed.

By signing the consent form below, you acknowledge that you understand the following:

1. You have been provided the "Fact Sheet for Patients, Parents and Caregivers" and been given an opportunity to read it.
2. Monoclonal antibody treatment with either bamlanivimab or casirivimab/imdevimab for COVID-19 is voluntary, and made available via Emergency Use Authorizations issued by the United States Food and Drug Administration (FDA).
3. The FDA has made bamlanivimab or casirivimab/imdevimab (monoclonal antibody) available for treatment of COVID-19 despite the fact that bamlanivimab and casirivimab/imdevimab are *not* FDA-approved drugs.
4. The decision to accept monoclonal antibody treatment with either bamlanivimab or casirivimab/imdevimab is *voluntary*, and you have the right to refuse or decline this therapy. If you decline this treatment, you will still be provided all standard treatments but your condition may deteriorate. Even with the recommended proposed treatment, your condition may deteriorate.
5. You have been informed of alternatives to receiving monoclonal antibody treatment.
6. While there are studies which suggest a potential for benefit, there is no scientifically proven results that this therapy is beneficial.
7. There are risks associated with monoclonal antibody treatment with either bamlanivimab or casirivimab/imdevimab. Adverse events have been reported. All potential risks are not known at this time.
8. After review of available information the FDA believed that the overall potential benefits appeared to outweigh the potential risks, and with relatively few alternative available therapies, it has made these products available through the Emergency Use Authorization program.
9. Your healthcare provider can offer additional information and answer questions at your request, to supplement the information available in the Fact Sheet provided to you.

The monoclonal antibody treatment that has been recommended for me is (choose one):

_____ **bamlanivimab** **or** _____ **casirivimab / imdevimab**

By signing below, I acknowledge that I have reviewed this document, understand its contents, and agree to receive monoclonal antibody treatment for COVID-19 under the Emergency Use Authorization program discussed above.

Patient printed name: _____

Patient signature: _____ Date: _____ Time: _____