30639

KENT HOSPITAL
Warwick, RI 02886

COMMUNITY REFERRAL FOR MONOCLONAL ANTIBODY TREATMENT FOR SARS-COV-2

PATIENT LABEL

C19-30639 (12-2020)

For Care New England referral office use only: #_____#_____#_____

Dear Provider: Thank you for referring your patient for a monoclonal antibody infusion against SARS-CoV-2 as an outpatient treatment that may decrease chance of hospitalization for COVID-19. Monoclonal antibody infusions are authorized under an FDA Emergency Use Authorization (EUA) are ***not indicated in patients requiring supplemental oxygen above their baseline (if on baseline O2, no increase in liters) or in those meeting criteria for hospitalization.*** *Due to limited supply, patients most likely to benefit will be prioritized.*

- ***To qualify for consideration, patients must:***
  - ***Weigh ≥40kg (88 lbs)***
  - ***Present within 10 days of symptom onset***
  - ***Have a positive test for SARS-CoV-2***
  - ***Not require supplemental O2 above their baseline*** *(if on baseline supplemental O2, no increase in liters required)*
  - ***Have a high risk of progressing to severe COVID-19 and/or hospitalization*** *(see APPENDIX page 2)*

Please supply the following information for our team to be able to assess your referral. Appointments may be limited by supply or availability and cannot be guaranteed. Thank you for referring your patient to our center.

PLEASE PRINT CLEARLY and fax <u>this form</u> and the <u>signed informed consent</u> to fax #401-889-5035
Incomplete / Illegible information may result in decreased prioritization; consent may be obtained virtually
If appointment needs to be cancelled, please call (401) 889-5899

Basic demographic information

Patient Name: _____

Date of Birth: _____ Age (years):_____

Gender: _____ Preferred Language: _____

Patient Scheduling Contact Name:_____Phone:_____
(*Needed for appointment scheduling, eg. may be patient, caregiver, etc.)*)

Referring Provider's name: _____Phone:_____
(*First/Last, print clearly*; *phone # for questions regarding eligibility)*

Accessibility: ☐ Patient is ambulatory ☐ Requires wheelchair ☐ Requires stretcher

COVID-19 related information

Date of symptom onset (*must be within 10 days of onset to qualify*):_____

Date of first positive test for SARS-CoV-2 (COVID-19): _____

Is the patient on home oxygen at baseline? ☐ Yes ☐ No

If yes, what is the patient's baseline oxygen requirement? _____ L/min

What is the patient's current oxygen requirement? ☐ None (room air) ☐ _____ L/min
(Note: patients on baseline room air who now require supplemental oxygen, or those with an increase in O2 liter requirement if on baseline oxygen, are not eligible)

Referring Provider has reviewed FDA EUA with patient/caregiver and has (*must select all below for eligibility)*:

- ☐ Given the "Fact Sheet for Patients, Parents and Caregivers"
- ☐ Informed of alternatives to receiving the COVID-19 antibody treatment
- ☐ Informed that the COVID-19 antibody is an unapproved drug that is authorized for use under this EUA

Patient/Caregiver agrees to proceed with COVID-19 antibody treatment and has signed consent form: ☐ Yes

If not patient, surrogate decision-maker name:_____

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PATIENT LABEL

*Patient Name:*_____*Date of Birth:*_____

Relevant Medical History

Patient's weight (kg): _____ Patient's height (in): _____ BMI: _____
(*Must weigh ≥40kg; 88 lbs)*

Current medications: _____
(*May attach med list to referral form)*

Allergies: NKDA _____

Past Medical History: _____

Is the patient pregnant?: ☐ Yes ☐ No

Please check if patient has history of any of the following for eligibility *(select all that apply)*:

- ☐ Age ≥ 65 years
- ☐ Body mass index (BMI) ≥35
- ☐ Chronic kidney disease
- ☐ Diabetes
- ☐ Immunosuppressive disease
- ☐ Currently receiving immunosuppressive treatment
- ☐ Age 55-64 years of age *(MUST ALSO check AT LEAST ONE below; cardiovascular, hypertension, and/or COPD):*
- ☐ Cardiovascular disease
- ☐ Hypertension
- ☐ Chronic obstructive pulmonary disease/other chronic respiratory disease

As the referring provider, I attest that the above information is correct as of the date/time below:

☐ Order SARS-CoV-2 monoclonal antibody IV once per protocol
(Patient will receive bamlanivimab or casirivimab/imdevimab (Regeneron) based on supply availability)

Referring Provider's Signature: _____ Date _____Time_____

APPENDIX:

Eligibility based on EUA: Must meet all criteria from 1-5

1. Confirmed Covid-19 (SARS-CoV-2) positive patient weighing at least 40kg
2. Patient presenting within 10 days of symptom onset
3. Patient is not requiring hospitalization and hospital admission is NOT anticipated
4. Patient is NOT requiring supplemental oxygen due to COVID-19 above their baseline (if on baseline supplemental O2, no increase in liter requirement)
5. Patient is at high risk for progressing to severe COVID-19 and/or hospitalization. In order to be considered high risk, patients MUST meet one of the following criteria:
   - Age ≥ 65 years
   - Age ≥ 55 years AND have at least one of the following conditions:
     - Cardiovascular disease
     - Hypertension
     - Chronic obstructive pulmonary disease/other chronic respiratory disease
     - Body mass index (BMI) ≥ 35
     - Chronic kidney disease
     - Diabetes
     - Immunosuppressive disease or receiving immunosuppressive therapies
   - Age 18-54 years AND have at least one of the following conditions:
     - BMI ≥ 35
     - Chronic kidney disease
     - Diabetes
     - Immunosuppressive disease or receiving immunosuppressive therapies

INFORMED CONSENT FOR MONOCLONAL ANTIBODY TREATMENT

PATIENT LABEL

C19-30637 (12-2020)

Patient Name: _____ **DOB:** _____

Diagnosis/Condition: _____ **MR#:** _____

I hereby authorize Care New England Hospitals (which includes but is not limited to Kent Hospital, Women & Infants Hospital, CNE Outpatient Units and all other entities within the Care New England Health System), through its physicians, pharmacists, employees, and any others who may be selected, to prescribe and administer a medication, also known as a monoclonal antibody treatment, for the treatment of mild to moderate coronavirus disease 2019 (COVID-19). I understand SARS-CoV-2 is the coronavirus that causes COVID-19 disease and that there is currently no proven treatment for this potentially serious condition.

It has been explained to me that medications used for monoclonal antibody treatment are unapproved investigational drugs that have been authorized for emergency use by the Food and Drug Administration (FDA).

1. I understand the FDA has issued an Emergency Use Authorization (EUA) to allow limited use of these medications for individuals 12 years of age and older, weighing at least 40kg, with positive results of direct SARS-CoV-2 viral testing and who may be at high risk for progressing to severe COVID-19 and/or hospitalization.

2. I have been told and understand that I meet the criteria to receive monoclonal antibody treatment.

3. I have been told and understand that at this time the monoclonal antibody treatment will be administered as a single IV infusion within 10 days of symptom onset and additional doses may or may not be necessary.

4. The nature, purpose, material risks and anticipated benefits of this treatment has been discussed with me. I understand that at this time there are no adequate, approved or available alternative treatments. I understand there are limited clinical data available for drugs used as monoclonal antibody treatment. I understand not all risks and benefits of these investigational drugs are known at this time and that serious and unexpected adverse events may occur that have not been previously known or reported.

5. I understand there is limited information about the safety and effectiveness of monoclonal antibody treatment for management of COVID-19. I understand possible side effects include but are not limited to: serious hypersensitivity reaction, including anaphylaxis, difficulty breathing, infusion related reactions such as fever, chills, nausea, headache, bronchospasm, hypotension, changes in my heartbeat, wheezing, swelling of my lips, face or throat, angioedema, throat irritation, rash including hives, itching,, sweating, muscle aches, dizziness and shivering. Additional side effects include but are not limited to pain, bleeding, bruising of the skin, soreness, swelling and possible infection at the injection site.

6. I understand that individuals who are severely ill with COVID have an increased risk of dying from the infection, regardless of what treatment is used. I understand that currently the experience with monoclonal antibody treatment is that it may help individuals who have mild to moderate COVID-19 from progressing to severe COVID-19 and becoming hospitalized.

7. I have been given and have read, or had read to me the *Fact Sheet For Patients, Parents And Caregivers/Emergency Use Authorization (EUA) Of Monoclonal Antibodies (Bamlanivimab And Casirivimab/Imdevimab) For Coronavirus Disease 2019 (Covid-19)*

8. I understand that the known risks and complications, including unforeseen and unknown risks, may occur.

PATIENT LABEL

9. I am aware that the practice of medicine is not an exact science. I acknowledge that no guarantee or promise has been made as to the outcome and success of my treatment with medications used for monoclonal antibody treatment.

10. I understand that my signature on this form does not guarantee that an adequate supply of medications used for monoclonal antibody treatment will be available or that I will be able to receive monoclonal antibody treatment.

Patient Consent/Virtual Consent:

I understand that no guarantees have been made to me regarding the results of this treatment and that it may or may not improve my condition. I have had sufficient opportunity to discuss my condition and treatment with my physician(s) and or their associate(s), and all of my questions have been answered to my satisfaction. I believe I have been given sufficient information and knowledge upon which to make an informed decision about receiving medications used for monoclonal antibody treatment. I have read, or had read to me, and understand the entire contents of this form. I hereby voluntarily authorize and consent to receive medications used for monoclonal antibody treatment.

_____ _____ _____

Date Time Patient Signature

If Legal Representative: _____ _____

Signature Relationship

Physician/Provider Declaration:

Whether provided in person or virtually, I confirm that this patient or legal representative has received a full explanation about the nature and purpose of monoclonal antibody treatment, the risks involved in receiving medications used for monoclonal antibody treatment, and treatment alternatives. The patient confirms that he/she has received answers to all his/her questions, and to the best of my knowledge, I believe the patient has been adequately informed and has consented.

_____ _____ _____

Date Time Signature

PLEASE NOTE: If patient consent was obtained virtually, please indicate by checking the box below, and enter a note in the patient's medical record.

☐ **Virtual Consent Obtained**

30005

KENT HOSPITAL
455 Toll Gate Rd. • Warwick, RI 02886

PATIENT FINANCIAL AGREEMENT & GENERAL CONSENT

PATIENT LABEL

768-00.02 (2-2020)

CONSENT TO TREATMENT:
I understand that my care will be provided according to my attending physician's orders. I understand that when I request care for my medical condition I am generally consenting to other medical treatments such as x-ray examinations, laboratory tests and minor procedures that my physician may order. I further understand that photographs, videotapes, audiotapes, digital or other recordings may be taken for identification purposes or to document my medicial condition or care. For major procedures, such as a surgery, my physician will explain them to me and I will be asked to sign a separate consent form.

HEALTH CARE EDUCATION:
I understand that Kent Hospital (hereinafter, "Hospital") is a teaching hospital where individuals in training, residents, fellows, medical students, nursing students and other health care students may be observers or participants in my care under the direct or indirect supervision of licensed practitioner(s).

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION:
I understand that Hospital can release all necessary health information for purposes of treatment, payment and healthcare operations as permitted by applicable law. This includes disclosures and/or requests by telephone, fax, photo copy or electronic means which may include HIV/AIDS related information, substance use disorder treatment information and information about diagnosis or treatment of mental illness, as permitted by law. I understand that this information may be shared with other treating providers, third party payers and any designated Caregiver, including, but not limited to, insurance companies (and their review organizations), managed care organizations, Medicare, Medicaid or other governmental payers that may provide coverage and reimbursement for services rendered to me by the Hospital, or other third parties, including information pertaining to my identity, prognosis, diagnosis, treatment or any other information necessary to establish my eligibility for insurance benefits. I understand that the Hospital will share my health information for treatment purposes through a Health Information Exchange (HIE), as permitted by law. I further understand that I can opt out of the Hospital sharing with a HIE by making an Opt Out request in writing.

I further release the Hospital and its employees from any liability arising from the release of this information to such persons/agencies, provided that the release of information is done substantially in accordance with applicable law.

WORKER'S COMPENSATION:
If my care is related to an accident at work, I understand that my employer's Workers' Compensation carrier will also have access to all information contained in my medical record.

ASSIGNMENT OF INSURANCE BENEFITS:
To the extent permitted by law, I irrevocably assign to Hospital and other providers furnishing services to the patient any and all benefits of any type arising out of any claim or policy of insurance insuring the patient or any willing party liable to the patient. I authorize and request that payment of insurance benefits be made on my behalf for any services furnished to me by or in the Hospital, including physician services.

FEDERAL MEDICARE BENEFITS:
I certify that the information given by me in applying for payment under Title XVIII of the Social Security Act is correct. I authorize any holder of medical or other information about me to release to the Social Security Administration and/or the Medicare program or their intermediaries or other agents any information needed for this or a related Medicare claim. I request payment of authorized benefits be made on my behalf. I assign the benefits payable for physician services to the physician or organizations furnishing the services or authorize such physician or organization to submit claims to Medicare for payment to me. I acknowledge and agree that, to the extent permitted by law, I am responsible for payment for any services provided not covered by Medicare.

FINANCIAL AGREEMENT/GUARANTEE OF PAYMENT:
I acknowledge that I am legally responsible for all charges incurred in connection with medical care and treatment provided by Hospital and physicians providing professional services to me through the Hospital (hereinafter "Physicians"). I agree and consent to medical care that has been or will be provided to the patient whose name appears above. For services rendered by the Hospital and Physicians, I guarantee payment of the account and agree to pay such account at the time services are rendered if it will not be paid by my insurance carrier or other third-party payer ("Payer"). I understand that Payer may require authorization prior to my receiving treatment and that it is my responsibility to obtain that prior authorization and know the coverage of my plan. I understand that receiving prior authorization does not guarantee that my Payer will pay because the benefits permitted depend upon my individual healthcare plan. I further understand that I am responsible for payment if my Payer deems Hospital or Physicians to be out of network. I acknowledge that if my child/dependent is cared for by Hospital or Physicians I will be responsible for payment for services provided under these same terms and conditions. I acknowledge and understand I may receive calls to the cellular and residential telephone numbers and any electronic communications to include text or emails I provided in my demographic information, including communications using any type of artificial or prerecorded voice or auto-dialer technologies made by or on behalf of the Hospital, its providers, assignees, agents, servicers, debt collectors, or any owner of a receivable for unpaid services or treatment provided to me by the Hospital or any of its providers.

PERSONAL BELONGINGS: I understand that I (the patient) am responsible for any and all personal valuables that I bring with me to the Hospital. I hereby release the Hospital from any liability for the loss or damage of any and all personal possessions which I choose to keep with me during my care and treatment.

SIGNATURE: I have read the information above or have had it read to me. I understand the information and have had my questions answered to my satisfaction. My signature below verifies that I have voluntarily consented to the above.

Signature of Patient	(Date/Time)
Signature of Authorized Representative	(Date/Time)
Relationship to Patient	
Signature of Witness	(Date/Time)

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF MONOCLONAL ANTIBODIES (Bamlanivimab and Casirivimab/Imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called a monoclonal antibody (bamlanivimab or casirivimab/imdevimab) 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 or casirivimab/imdevimab, which you may receive.

Receiving bamlanivimab or casirivimab/imdevimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about bamlanivimab and casirivimab/imdevimab. Talk to your healthcare provider if you have questions. It is your choice to receive a monoclonal antibody or stop 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 occur 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 SYMPTOMSOF 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 ARE MONOCLONAL ANTIBODIES (BAMLANIVIMAB and CASIRIVIMAB/IMDEVIMAB)?

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

The FDA has authorized the emergency use of casirivimab and imdevimab for the treatment of COVID19 under an Emergency Use Authorization (EUA). For more information on EUA, see the “What is an Emergency Use Authorization (EUA)?” section at the end of this Fact Sheet.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE BAMLANIVIMAB or CASIRIVIMAB/IMDEVIMAB?

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 or CASIRIVIMAB/IMDEVIMAB?

- You will receive one dose of either bamlanivimab or casirivimab/imdevimab by intravenous infusion.
- Bamlanivimab is an investigational medicine given as a single intravenous infusion (through a vein) for at least 1 hour.
- Casirivimab/imdevimab are two investigational medicines given together as a single intravenous infusion (through a vein) for at least 1 hour.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF BAMLANIVIMAB AND CASIRIVIMAB/IMDEVIMAB?

Possible side effects of bamlanivimab and casirivimab/imdevimab are:

- Allergic reactions: Allergic reactions can happen during and after infusion with bamlanivimab or casirivimab/imdevimab. Tell your healthcare provider or nurse, or get medical help right away if you get any of the following signs and symptoms of allergic reactions:
    - fever, chills, low blood pressure, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, rash including hives, itching, headache, nausea, vomiting, sweating, muscle aches, dizziness and shivering.

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

It is possible that bamlanivimab and casirivimab/imdevimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab and casirivimab/imdevimab 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 and casirivimab/imdevimab, 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 other medicines used to treat people with COVID-19.

It is your choice to be treated or not to be treated with a monoclonal antibody (bamlanivimab and casirivimab/imdevimab). Should you decide not to receive a monoclonal antibody 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 and casirivimab/imdevimab. For a mother and unborn baby, the benefit of receiving bamlanivimab or casirivimab/imdevimab 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 AND CASIRIVIMAB/IMDEVIMAB?

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 or call 1-800-FDA-1088 or call

- 1-855-LillyC19 (1-855-545-5921) for bamlanivimab (Eli Lilly and Company)
- 1-844-734-6643 for casirivimab/imdevimab (Regeneron Pharmaceuticals)

HOW CAN I LEARN MORE?

- Ask your health care provider.
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.
- For bamlanivimab, visit www.bamlanivimab.com
- For casirivimab/imdevimab, visit www.REGENCOV2.com

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made bamlanivimab and casirivimab/imdevimab 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 and casirivimab/imdevimab have 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, 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 and casirivimab/imdevimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Literature issued and Authorized November 2020

Spanish versions for each monoclonal antibody can be found at:

Bamlanivimab: http://pi.lilly.com/eua/span/bamlanivimab-eua-factsheet-patient-span.pdf

Casirivimab/imdevimab: https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-patient-spanish.pdf

Bamlanivimab manufactured by:
Eli Lilly and Company, Indianapolis, IN 46285, USA

Casirivimab/imdevimab manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707