WashingtonRegional Medical Center

COVID Monoclonal Antibody Referral

Washington Regional Community Support Initiative
3318 N. Northhills Blvd
Phone 479-463-5555 **Fax** 479-463-5559
Email: wrmc_schedule@wregional.com

See inclusion and exclusion criteria for COVID monoclonal antibody (MAb) treatment on page 2.

- **Clinical staff will triage referral request and notify patient if they meet criteria for treatment. If patient does not meet criteria the requesting provider will be notified.**

December 2021 Updates

- Due to current supply changes, current order sets for MAb injections will be temporarily retired (12/1/2021)
- MAb therapy will be ordered under a referral based on patient specific criteria
  - Immunocompromised (definition below) regardless of vaccine status will be scheduled to receive *Casirivimab and imdevimab (Regen-COV*) injection for treatment of Covid-19 infection (present for less than 10 days) or post-exposure prophylaxis
  - Unvaccinated or partially vaccinated (including missing booster) and at least one risk factor (see below) will be scheduled to receive *Bamlanivimab plus etesevimab* infusion for treatment of Covid-19 infection (present for less than 10 days) or post exposure prophylaxis.
- Post exposure prophylaxis can be considered for individuals who meet the criteria above
  - **And** who meet close contact criteria per Centers for Disease Control and Prevention as exposure to an individual infected with SARS-CoV-2 (laboratory-confirmed or a clinically compatible illness) for a cumulative total of 15 minutes or more over a 24-hour period.
  - **Or** who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

Patient Consent

- Casirivimab and imdevimab (Regen-COV) pages 3-5
- Bamlanivimab and etesevimab page 6-8

Complete both consents forms.

Patient FDA Fact Sheets

- Casirivimab and imdevimab (Regen-COV) pages 9-12
- Bamlanivimab and etesevimab page 13-16

Upon reviewing FACT sheet and consent with patient, return referral pages (2) and **signed** consent [(4-9) Must be signed by patient and provider prior to fax]. **Please also send a current clinic note and demographics.**

Note: preparation of some mAb regimens takes ~ 1 hour for the pharmacy to prepare. Some patients may be at WRMC at least 3 hours.

COVID Monoclonal Antibody Referral

WashingtonRegional Medical Center

Patient Name: _____ **Today's Date:** _____

SSN: _____ **Date of Birth:** _____ **Weight (kg):** _____

Allergies: _____ **Patient's Phone:** _____

Diagnosis: _____ **ICD 10:** _____

Insurance(s):

Consent	☐ Signed consent to accompany this order		
COVID Vaccine History (if applicable)	Vaccine Manu./ Date received (#1) _____	Vaccine Manu./ Date received (#2) _____	Vaccine Manu./ Date received (booster) _____

Patient Referral Selection

- Immunocompromised (definition below) regardless of vaccine status will be scheduled to receive *Casirivimab and imdevimab (Regen-COV)* injection for treatment of Covid-19 infection (present for less than 10 days) or post-exposure prophylaxis
- Unvaccinated or partially vaccinated (including missing booster) and at least one risk factor (see below) will be scheduled to receive *Bamlanivimab plus etesevimab* infusion for treatment of Covid-19 infection (present for less than 10 days) or post exposure prophylaxis.

Exclusion Criteria: *patients will not meet criteria under the EUA, do not continue with ordering if ANY of the below are true.*

- ☐ Age < 12
- ☐ Weight < 40kg
- ☐ Lack of positive SARS-CoV-2 test (unless meeting criteria for post exposure prophylaxis)
- ☐ Hospitalized patient (unless hospitalized for other illness and infection is discovered or exposure occurs while hospitalized)
- ☐ COVID+ requiring oxygen OR increased in baseline oxygen needs due to COVID-19 in those on chronic oxygen
- ☐ Patient experiencing COVID symptoms for greater than 10 days
- ☐ Fully vaccinated (initial series + booster) patients (including high risk patients) not meeting criteria for immunocompromised (below)

Definition of immunocompromised is as follows:	**Treatment or post-exposure prophylaxis for any vaccination status**
☐ Been receiving active cancer treatment for tumors or cancers of the blood ☐ Received an organ transplant and are taking immunosuppressive therapy ☐ Received a stem cell transplant within the last 2 years or who are taking immunosuppressive therapy ☐ Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome) ☐ Advanced or untreated HIV infection. Advanced HIV is defined as people with CD4 T lymphocyte cell counts <200/mm^3, a history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV. ☐ Active treatment with high-dose steroids or other immunosuppressive drugs	**Casirivimab 600mg + imdevimab 600mg (Regen-COV) by subcutaneous injection**

Risk factors for severe disease are as follows (≥1 below):	**Treatment or post-exposure prophylaxis for unvaccinated or partially vaccinated**
☐ ≥ 65 ☐ Racial and ethnic minority ☐ People with disabilities ☐ Cancer not meeting immunosuppressed definition ☐ Chronic kidney disease ☐ Chronic liver disease ☐ Chronic lung disease (including COPD, asthma, CF, Tuberculosis) ☐ Dementia or neurological condition ☐ Diabetes (Type 1 or 2) ☐ Down Syndrome ☐ Heart conditions (cardiovascular disease or hypertension) ☐ HIV not meeting immunosuppressed definition ☐ Mental Health conditions ☐ Overweight BMI ≥ 25 ☐ Pregnancy ☐ Sickle Cell disease or Thalassemia ☐ Smoker or Substance use disorder ☐ Stroke	**Bamlanivimab 700mg + etesevimab 1400mg in normal saline IV infusion** *Provider: MAb treatment Referral Protocol available which include monitoring, infusion reaction response.*

_____ _____ _____

Referral for Treatment Protocol Physician's Signature | Print Physician's Name | Time / Date

Please fax to 463-5559 or email per cover sheet. Please send copy of insurance card, clinic notes and all information requested with order. PHYSICIAN MUST SIGN, DATE, and TIME order. **Please encourage patients to bring home medications** and refreshments for their comfort. Updated: 12-1-21

PHY045

Patient Consent to Administration of CASIRIVIMAB AND IMDEVIMAB for Patient Diagnosed with COVID-19

This is a consent for emergency use of Casirivimab and imdevimab administration to patients with COVID-19 or patients at high risk for progression to severe COVID-19 after exposure. ***Casirivimab and imdevimab has not been approved by the U.S. Food and Drug Administration (FDA) though the FDA has authorized the emergency use of casirivimab and imdevimab for certain patients 12 years of age or older who have mild to moderate coronavirus disease 2019 (COVID-19) or have been exposed to COVID-19 and who are at high risk of progressing to severe COVID-19 and/or hospitalization.***

Your physician is recommending that you receive casirivimab and imdevimab because you have been diagnosed with mild to moderate COVID-19 disease or have been exposed to COVID-19 and you are considered to be at high risk of progressing to severe COVID-19 disease and/or being hospitalized. Your physician believes casirivimab and imdevimab may help reduce the severity of COVID-19 illness and aid efforts to prevent the COVID-19 illness from worsening and/or resulting in your having to be admitted to a hospital for further treatment. There are currently no approved drugs or other therapeutic agents for the treatment of mild to moderate COVID-19 but casirivimab and imdevimab may present the best available therapy for assisting your body to fight this virus.

Please read this information carefully. It provides important details about the use of casirivimab and imdevimab for patients with mild to moderate COVID-19 disease. casirivimab and imdevimab is regulated by the Food & Drug Administration (FDA), but importantly has not been approved by the FDA. Your physician has recommended its use because you have been confirmed to have mild to moderate COVID-19 disease or have been exposed to COVID-19, and you are considered by your physician to be at high risk of progressing to severe COVID-19 disease that may possibly require hospitalization. There is no comparable or satisfactory alternative therapy to treat COVID-19. Your physician will talk to you about the risks and potential benefits to receiving casirivimab and imdevimab. Please take your time to make your decision. Discuss this matter with your family, friends and healthcare provider before you make your decision. ***Note:*** If you are a family member or legally authorized representative signing this consent form for the patient, "you" in the consent form refers to the patient with COVID-19.

What is casirivimab and imdevimab and why is my physician recommending that I receive it? You have been diagnosed with or have been exposed to disease caused by the SARS-CoV-2 virus, also known as coronavirus disease 2019 (COVID-19). COVID-19 is a respiratory virus that has been associated with a wide range of symptoms such as fever or chills, cough, shortness of breath or difficulty breathing, fatigue, headache, muscle or body aches, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea. In more severe cases, symptoms may include failure of the ability to breathe or even death.

Your physician is asking you to consider having casirivimab and imdevimab administered to you subcutaneously to aid in the management of COVID-19 disease because you are at high-risk of progressing to severe COVID-19 disease that may require your admission to a hospital.

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:
• Older age (for example, age ≥65 years of age)
• Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
• Pregnancy
• Chronic kidney disease
• Diabetes
• Immunosuppressive disease or immunosuppressive treatment
• Cardiovascular disease (including congenital heart disease) or hypertension
• Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
• Sickle cell disease
• Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
• Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

Casirivimab and imdevimab may aid the treatment of COVID-19 in adults and adolescents 12 years of age and older who have mild to moderate symptoms of COVID-19 disease.
The FDA grants emergency use authorization to provide availability of a medicine that may help diagnose, treat or prevent a life-threatening disease when no adequate and approved alternatives are available. Casirivimab and imdevimab is a monoclonal antibody that has been scientifically engineered to attach to and destroy an antigen unique to the COVID-19 virus. It is designed to block viral attachment and entry into human cells, thus neutralizing the virus, potentially treating COVID-19. An ***antibody*** is a protein that sticks to a specific protein called an ***antigen***. Antibodies circulate throughout the body until they find and attach to the antigen. Once attached, they can force other parts of the immune system to destroy the cells containing the antigen. Researchers can design antibodies that specifically target a certain antigen, such as one found on COVID-19 virus cells. They can then make many copies of that antibody in the lab. These are known as *monoclonal antibodies.* In limited clinical trials, patients treated with the casirivimab and imdevimab monoclonal antibody showed reduced viral load and rates of symptoms and hospitalization.

It is not known with certainty whether this treatment will or will not help you. This treatment, in uncommon instances, has been known to cause harmful side effects such as anaphylaxis shock (signs of which include, sudden drop in blood pressure and narrowing of airways, resulting in blocked breathing; a rapid, weak pulse; skin rash, nausea and vomiting). The most common reported side effects are nausea, diarrhea, dizziness, headache, severe itching and vomiting. This is one of the only treatments that we have available at this time, but you need to know that it has not yet been proven to work. Because you have been diagnosed with mild to moderate COVID-19 disease or have been exposed to COVID-19 and are at high-risk to progress to severe COVID-19 disease which may require hospitalization, and because we do not currently have any better treatment options, we are asking you to consider having casirivimab and imdevimab administered to you as part of the effort to treat your COVID-19 illness.

Is this an approved therapy?
Casirivimab and imdevimab is experimental and is not approved by the Food and Drug Administration (FDA), but is allowed by the FDA for emergency use only.

What is involved in receiving this therapy?
You will be given Casirivimab and imdevimab by subcutaneous injection. A single 1200 mg dose of medication will be given in this injection. Additional injections of Casirivimab and imdevimab may occur as directed by your physician, provided your physician determines that additional treatments are clinically appropriate. One dose will consist of 4 subcutaneous injections given in separate locations around the same time.

What are the possible risks of receiving this therapy?
There is limited information at this point in time concerning the safety of casirivimab and imdevimab. Possible side effects associated with the administration of casirivimab and imdevimab include allergic reactions, the symptoms of which include, fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of the lips, face or throat, rash, including hives, itching, muscle aches, and dizziness.
The risks to pregnant women or breastfeeding mothers are unknown. While the benefit to receiving casirivimab and imdevimab may be greater than the risk from the treatment, you should discuss your specific situation and options with your physician if you are pregnant or breastfeeding.
You may have other side effects that are not known at this time and may include serious injury or pain, disability or death.

What are the possible benefits to receiving casirivimab and imdevimab?
We do not know if casirivimab and imdevimab will be an effective treatment for COVID-19, and you might not experience any benefit. However, your physician believes that this treatment might be effective in improving the likelihood of your recovering from COVID-19 disease and/or reducing the likelihood that your COVID-19 disease may become severe and/or require your hospitalization.
Can I change my mind after I sign this form?
Yes, at any time. You can choose to get this treatment or not. Your choice will not affect the care that you are receiving at Washington Regional. We will always do our best to take care of you.

What other treatment choices are there?
Like casirivimab and imdevimab, FDA may allow for the emergency use of other medicines to treat people diagnosed with COVID-19. Go to www.cdc.gov/COVID19 for information on the emergency use of other medicines that are not approved by FDA to treat people in the hospital 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 with casirivimab and imdevimab. Should you decide not to receive it or stop it at any time, it will not change your standard medical care.

Consent to Receive Casirivimab and imdevimab
By signing this informed consent document, I am agreeing to receive an injection of casirivimab and imdevimab in conjunction with my treatment or post-exposure prophylaxis for mild to moderate COVID-19 disease. I have not given up any of my legal rights or released any individual or institution from liability for negligence. I have discussed with my physician the risks and benefits associated with the administration of casirivimab and imdevimab to me and I have had an opportunity to ask my physician any questions that I might have. My physician has advised me that there are no FDA approved therapies for the treatment or prophylaxis of mild to moderate COVID-19. Casirivimab and imdevimab is NOT approved by the FDA. My physician has further explained to me the significant known and potential risks and benefits of casirivimab and imdevimab, and the extent to which such risks and benefits are unknown. My physician has also informed me of alternatives to receiving casirivimab and imdevimab.

I acknowledge that I have been provided a copy of this informed consent document and the *Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) Of Casirivimab and imdevimab for Coronavirus Disease 2019 (COVID-19) ("Fact Sheet")* prepared and recommended to me for review by the U.S. Food and Drug Administration. I acknowledge that I have had an opportunity to read the Fact Sheet provided to me and have had an opportunity to discuss the same with my physician. The information was read to me or my authorized representative if I am unable to read.

I agree that I have read this form or have had it read to me and I have had any questions or concerns that I have regarding the administration or purpose of casirivimab and imdevimab fully and adequately explained to me and that by signing below, I acknowledge and consent to the administration of casirivimab and imdevimab for the treatment of my COVID-19 illness knowing the risks associated with the emergency use of this drug.
I understand that I will be given a copy of this informed consent document. I further acknowledge that this document was read to me if I made such a request.

_____
Printed Name of Patient

_____ _____
Signature (Patient or Authorized Representative) Date

Consenting Provider
I have explained the treatment to the patient/authorized representative and have answered all questions about this treatment to the best of my ability.

_____
Printed Name

_____ _____
Signature Date and Time

Where applicable:

_____ _____
Interpreter Signature and Language Used Date and Time

Patient Consent to Administration of BAMLANIVIMAB AND ETESEVIMAB for Patient Diagnosed with COVID-19

This is a consent for emergency use of bamlanivimab and etesevimab administration to patients with COVID-19 or patients at high risk for progression to severe COVID-19 after exposure. ***Bamlanivimab and etesevimab has not been approved by the U.S. Food and Drug Administration (FDA) though the FDA has authorized the emergency use of bamlanivimab and etesevimab for certain patients 12 years of age or older who have mild to moderate coronavirus disease 2019 (COVID-19) or have been exposed to COVID-19 and who are at high risk of progressing to severe COVID-19 and/or hospitalization.***

Your physician is recommending that you receive bamlanivimab and etesevimab because you have been diagnosed with mild to moderate COVID-19 disease and you are considered to be at high risk of progressing to severe COVID-19 disease or have been exposed to COVID-19 and/or being hospitalized. Your physician believes bamlanivimab and etesevimab may help reduce the severity of your COVID-19 illness and aid efforts to prevent your COVID-19 illness from worsening and/or resulting in your having to be admitted to a hospital for further treatment. There are currently no approved drugs or other therapeutic agents for the treatment of mild to moderate COVID-19 but bamlanivimab and etesevimab may present the best available therapy for assisting your body to fight this virus.

Please read this information carefully. It provides important details about the use of bamlanivimab and etesevimab for patients with mild to moderate COVID-19 disease. Bamlanivimab and etesevimab is regulated by the Food & Drug Administration (FDA), but importantly has not been approved by the FDA. Your physician has recommended its use because you have been confirmed to have mild to moderate COVID-19 disease or have been exposed to COVID-19, and you are considered by your physician to be at high risk of progressing to severe COVID-19 disease that may possibly require hospitalization. There is no comparable or satisfactory alternative therapy to treat COVID-19. Your physician will talk to you about the risks and potential benefits to receiving bamlanivimab and etesevimab. Please take your time to make your decision. Discuss this matter with your family, friends and healthcare provider before you make your decision. ***Note:*** If you are a family member or legally authorized representative signing this consent form for the patient, "you" in the consent form refers to the patient with COVID-19.

What is bamlanivimab and etesevimab and **why is my physician recommending that I receive it?** You have been diagnosedwith or have been exposed to disease caused by the SARS-CoV-2 virus, also known as coronavirus disease 2019 (COVID-19). COVID-19 is a respiratory virus that has been associated with a wide range of symptoms such as fever or chills, cough, shortness of breath or difficulty breathing, fatigue, headache, muscle or body aches, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea. In more severe cases, symptoms may include failure of the ability to breathe or even death.

Your physician is asking you to consider having bamlanivimab and etesevimab administered to you intravenously to aid in the management of your mild to moderate COVID-19 disease because you are at high-risk of progressing to severe COVID-19 disease that may require your admission to a hospital.

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:

- Older age (for example, age ≥65 years of age)
- Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

COVID Monoclonal Antibody Referral

Bamlanivimab and etesevimab may aid the treatment of COVID-19 in adults and adolescents 12 years of age and older who have mild to moderate symptoms of COVID-19 disease.

The FDA grants emergency use authorization to provide availability of a medicine that may help diagnose, treat or prevent a life-threatening disease when no adequate and approved alternatives are available. Bamlanivimab and etesevimab is a monoclonal antibody that has been scientifically engineered to attach to and destroy an antigen unique to the COVID-19 virus. It is designed to block viral attachment and entry into human cells, thus neutralizing the virus, potentially treating COVID-19. An ***antibody*** is a protein that sticks to a specific protein called an ***antigen***. Antibodies circulate throughout the body until they find and attach to the antigen. Once attached, they can force other parts of the immune system to destroy the cells containing the antigen. Researchers can design antibodies that specifically target a certain antigen, such as one found on COVID-19 virus cells. They can then make many copies of that antibody in the lab. These are known as *monoclonal antibodies.* In limited clinical trials, patients treated with bamlanivimab and etesevimab monoclonal antibody showed reduced viral load and rates of symptoms and hospitalization.

It is not known with certainty whether this treatment will or will not help you. This treatment, in uncommon instances, has been known to cause harmful side effects such as anaphylaxis shock (signs of which include, sudden drop in blood pressure and narrowing of airways, resulting in blocked breathing; a rapid, weak pulse; skin rash, nausea and vomiting). The most common reported side effects are nausea, diarrhea, dizziness, headache, severe itching and vomiting. This is one of the only treatments that we have available at this time, but you need to know that it has not yet been proven to work. Because you have been diagnosed with mild to moderate COVID-19 disease or have been exposed to COVID-19 and are at high-risk to progress to severe COVID-19 disease which may require hospitalization, and because we do not currently have any better treatment options, we are asking you to consider having bamlanivimab and etesevimab administered to you as part of the effort to treat your COVID-19 illness.

Is this an approved therapy?
Bamlanivimab and etesevimab is experimental and is not approved by the Food and Drug Administration (FDA), but is allowed by the FDA for emergency use only.

What is involved in receiving this therapy?
You will be given bamlanivimab and etesevimab by intravenous infusion, meaning the drug will be delivered through one of your veins, using a sterile single use needle, which will be given over the course of about one to two hours. A single 700 mg dose of medication will be given in this infusion. Additional infusions of bamlanivimab and etesevimab may occur as directed by your physician, provided your physician determines that additional treatments are clinically appropriate.

What are the possible risks of receiving this therapy?
There is limited information at this point in time concerning the safety of bamlanivimab and etesevimab. Possible side effects associated with the administration of bamlanivimab and etesevimab include allergic reactions, the symptoms of which include, fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of the lips, face or throat, rash, including hives, itching, muscle aches, and dizziness.
The risks to pregnant women or breastfeeding mothers are unknown. While the benefit to receiving bamlanivimab and etesevimab may be greater than the risk from the treatment, you should discuss your specific situation and options with your physician if you are pregnant or breastfeeding.
You may have other side effects that are not known at this time and may include serious injury or pain, disability or death.

What are the possible benefits to receiving bamlanivimab and etesevimab?
We do not know if bamlanivimab and etesevimab will be an effective treatment for COVID-19, and you might not experience any benefit. However, your physician believes that this treatment might be effective in improving the likelihood of your recovering from COVID-19 disease and/or reducing the likelihood that your COVID-19 disease may become severe and/or require your hospitalization.

Can I change my mind after I sign this form?
Yes, at any time. You can choose to get this treatment or not. Your choice will not affect the care that you are receiving at Washington Regional. We will always do our best to take care of you.

What other treatment choices are there?
Like bamlanivimab and etesevimab, FDA may allow for the emergency use of other medicines to treat people diagnosed with COVID-19. Go to www.cdc.gov/COVID19 for information on the emergency use of other medicines that

are not approved by FDA to treat people in the hospital 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 with bamlanivimab and etesevimab. Should you decide not to receive it or stop it at any time, it will not change your standard medical care.

Consent to Receive bamlanivimab and etesevimab

By signing this informed consent document, I am agreeing to receive an infusion of Bamlanivimab and etesevimab in conjunction with my treatment or post-exposure prophylaxis for mild to moderate COVID-19 disease. I have not given up any of my legal rights or released any individual or institution from liability for negligence. I have discussed with my physician the risks and benefits associated with the administration of bamlanivimab and etesevimab to me and I have had an opportunity to ask my physician any questions that I might have. My physician has advised me that there are no FDA approved therapies for the treatment or prophylaxis of mild to moderate COVID-19. Bamlanivimab and etesevimab is NOT approved by the FDA. My physician has further explained to me the significant known and potential risks and benefits of bamlanivimab and etesevimab, and the extent to which such risks and benefits are unknown. My physician has also informed me of alternatives to receiving bamlanivimab and etesevimab.

I acknowledge that I have been provided a copy of this informed consent document and the *Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) Of bamlanivimab and etesevimab for Coronavirus Disease 2019 (COVID-19) ("Fact Sheet")* prepared and recommended to me for review by the U.S. Food and Drug Administration. I acknowledge that I have had an opportunity to read the Fact Sheet provided to me and have had an opportunity to discuss the same with my physician. The information was read to me or my authorized representative if I am unable to read.

I agree that I have read this form or have had it read to me and I have had any questions or concerns that I have regarding the administration or purpose of bamlanivimab and etesevimab fully and adequately explained to me and that by signing below, I acknowledge and consent to the administration of bamlanivimab and etesevimab for the treatment of my COVID-19 illness knowing the risks associated with the emergency use of this drug.
I understand that I will be given a copy of this informed consent document. I further acknowledge that this document was read to me if I made such a request.

_____
Printed Name of Patient

_____ _____
Signature (Patient or Authorized Representative) Date

Consenting Provider

I have explained the treatment to the patient/authorized representative and have answered all questions about this treatment to the best of my ability.

_____
Printed Name

_____ _____
_____ _____
Signature Date and Time

Where applicable:

_____ _____
Interpreter Signature and Language Used Date and Time

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™
(casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.
Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.
Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?
COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. 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, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people 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 REGEN-COV (casirivimab and imdevimab)?
REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:
• treatment of mild to moderate symptoms of COVID-19
• post-exposure prevention of COVID-19 in persons who are: o not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**,
o are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications),
and
□have been exposed to someone who is infected with SARS-CoV-2.Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet fora total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for

example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to

https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html,**or**

□someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to preventCOVID-19in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19and the post-exposure prevention of COVID-19under 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.

WHO SHOULD NOT TAKE REGEN-COV?
Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?
Tell your healthcare provider about all of your medical conditions, including if you:
•Have any allergies
•Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
•Have received a COVID-19 vaccine.
•Have any serious illnesses
•Are pregnant or plan to become pregnant
•Are breastfeeding or plan to breastfeed
•Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?
•REGEN-COV consists of two investigational medicines, casirivimab and imdevimab,given together at the same time through a vein (intravenous or IV) or injected in the tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**
• Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion. o If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.

• Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. o After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?

Possible side effects of REGEN-COV are:

• Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.

• Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

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. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

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

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV 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 REGEN-COV (casirivimab and imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA that are used 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 REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?

Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTSWITH REGEN-COV (casirivimab and 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 1-844-734-6643.

HOW CAN I LEARN MORE?
- Ask your health care provider.
- Visit www.REGENCOV.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 REGEN-COV (casirivimab and 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.
REGEN-COV has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.
The EUA for REGEN-COV 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).

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

You are being given two medicines together called **bamlanivimab and etesevimab** for the treatment or post-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab and etesevimab.

Receiving bamlanivimab and etesevimab may help to treat COVID-19 in certain people, or help to prevent COVID-19 in certain people who have been exposed to someone infected with SARS-CoV-2 or who are at high risk of an exposure because of where they live, such as nursing homes or prisons.

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

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. 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, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people 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 are bamlanivimab and etesevimab?
Bamlanivimab and etesevimab are investigational medicines used together in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for developing severe COVID-19, including hospitalization or death for:

- **treatment** of mild to moderate symptoms of COVID-19, OR
- **post-exposure prophylaxis for prevention** of COVID-19 in persons who are:
  - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**
  - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications), **and**
    - have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, **or**

- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

Bamlanivimab and etesevimab are investigational because they are still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab and etesevimab to treatment or prevention of COVID-19. Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of bamlanivimab and etesevimab together for the treatment of COVID-19 and the post-exposure prophylaxis for prevention 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 and etesevimab?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have received a COVID-19 vaccine
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How will I receive bamlanivimab and etesevimab?

- Bamlanivimab and etesevimab are given to you at the same time through a vein (intravenous or IV).
- You will receive one dose of bamlanivimab and etesevimab by IV infusion. The infusion will take 21 – 60 minutes or longer. Your healthcare provider will determine the duration of your infusion.

What are the important possible side effects of bamlanivimab and etesevimab?

Possible side effects of bamlanivimab and etesevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab and etesevimab. 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 or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness, and sweating. These reactions may be severe or life threatening.
- Worsening of COVID-19 symptoms after bamlanivimab and etesevimab therapy for active infection: You may experience new or worsening symptoms after infusion for mild to moderate COVID-19, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

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 etesevimab. Not a lot of people have been given bamlanivimab and etesevimab. Serious and unexpected side effects may happen. Bamlanivimab and etesevimab 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 etesevimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab and etesevimab 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 etesevimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization 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 and etesevimab. Should you decide not to receive bamlanivimab and etesevimab or stop it at any time, it will not change your standard medical care.

What other prevention choices are there?
Vaccines to prevent COVID-19 are approved or available under Emergency Use Authorization. Use of bamlanivimab and etesevimab does not replace vaccination against COVID-19.

Like bamlanivimab and etesevimab, FDA may allow for the emergency use of other medicines for post-exposure prophylaxis for prevention of COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA for post-exposure prophylaxis for prevention of COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab and etesevimab. For a mother and unborn baby, the benefit of receiving bamlanivimab and etesevimab 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 etesevimab?
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.LillyAntibody.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 and etesevimab 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 etesevimab have not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for bamlanivimab and etesevimab together 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).

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