AFFIX PATIENT LABEL HERE

COVID monoclonal antibody treatment

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

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

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

Diagnosis: _____ **ICD 10:** _____

Insurance(s):

Intravenous Access	☐ Insert peripheral IV and discontinue prior to discharge. ☐ Saline Flush 2.5mL as needed for peripheral access ☐ Saline Flush 10mL as needed for central access	☐ Heparin 100units/mL inj, 250 units IV for access/port ☐ Other: _____
Vital Signs	☑ Per unit protocol ☐ Other: _____	
Consent	☐ Signed consent to accompany this order	

Medication Orders (include drug, dose, route, frequency, duration):

Bamlanivimab and Casirivimab/imdevimab used under an Emergency Use Authorization (EUA). The EUA is for the use of the unapproved product **Bamlanivimab and Casirivimab/imdevimab** for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

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
- ☐ Patient hospitalized for COVID-19
- ☐ COVID+ requiring oxygen OR increased in baseline oxygen needs due to COVID-19 in those on chronic oxygen
- ☐ Patient experiencing COVID-19 symptoms for greater than 10 days

Inclusion Criteria: *Patient must have confirmed COVID+ test and meet one of the following to qualify for treatment. Select criteria for inclusion below.*

- ☐ Have a body mass index (BMI) ≥35
- ☐ Have chronic kidney disease
- ☐ Have diabetes
- ☐ Have immunosuppressive disease
- ☐ Are currently receiving immunosuppressive treatment
- ☐ Are ≥65 years of age
- ☐ <u>Are ≥55 years of age AND</u> have at least one of the following:
  - ☐ cardiovascular disease, OR
  - ☐ hypertension, OR
  - ☐ chronic obstructive pulmonary disease/other chronic respiratory disease.
- ☐ <u>Are 12 – 17 years of age AND</u> have one of the following:
  - ☐ BMI ≥85th percentile for their age and gender based on CDC growth charts, OR
  - ☐ sickle cell disease, OR
  - ☐ congenital or acquired heart disease, OR
  - ☐ neurodevelopmental disorders, for example, cerebral palsy, OR
  - ☐ a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - ☐ asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Select one monoclonal antibody to order. In the event of medication shortage, the other monoclonal antibody will automatically be substituted per P&T approval unless indicated below.

- ☐ **Bamlanivimab 700 mg in 200mls normal saline IV infusion. Infuse over 1 hour.**
  - Infuse through PVC infusion set with a 0.2/0.22 micron in-line filter
  - After infusion has completed, confirm drug bag has infused completely and flush entire line after dose to ensure entire dose has been administered.
  - Monitor patient during infusion and at least 1 hour after infusion.

- ☐ **Casirivimab 1200mg + imdevimab 1200mg in 250mL normal saline IV infusion. Infuse over 1 hour.**
  - Infuse through PVC infusion set with a 0.2/0.22 micron in-line filter
  - After infusion has completed, confirm drug bag has infused completely and flush entire line after dose to ensure entire dose has been administered.
  - Monitor patient during infusion and at least 1 hour after infusion.

Give 30 minutes prior to infusion. *There is no recommendation that pre-medications are required with casirivimab and imdevimab.*

- ☐ Acetaminophen PO 975mg ONCE *confirm patient hasn't taken prior to arrival or within the last 4 hours*
- ☐ Diphenhydramine PO 50mg ONCE OR _____
- ☐ Methylprednisolone IV ☐125 mg once OR ☐_____

Infusion-related reactions have been observed with administration of casirivimab and imdevimab. 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 administer appropriate medications and/or supportive care.

In the event that an infusion reaction occurs, the following medications may be needed until further orders are received:

- ☑ Epinephrine 1 mg/mL inj aqueous solution (1:1000 dilution) 0.3 mg/0.3 mL IM administered to the mid-outer thigh. May be repeated.
- ☑ Optional treatment (this is for itching and urticaria, DOES NOT RELIEVE upper or lower airway obstruction, hypotension or shock): H1 Antihistamine: Diphenhydramine: 25mg IV once

All side effects must be reported to FDA MedWatch.

Substitution permitted. Physician's Signature	Print Physician's Name	Time / Date
***Dispense as written*, do not substitute in the event of supply changes.** Physician's Signature	Print Physician's Name	Time / Date

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

This is a consent for emergency use of Bamlanivimab administration to patients with COVID-19. ***Bamlanivimab has not been approved by the U.S. Food and Drug Administration (FDA) though the FDA has authorized the emergency use of Bamlanivimab for certain patients 12 years of age or older who have mild to moderate coronavirus disease 2019 (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 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 and/or being hospitalized. Your physician believes Bamlanivimab 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 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 for patients with mild to moderate COVID-19 disease. Bamlanivimab 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, 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. 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 why is my physician recommending that I receive it? You have been diagnosed with 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 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.
A patient is considered "high-risk" if they meet at least one of the following criteria:

- Have a body mass index (BMI) of ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age AND HAVE
    - Cardiovascular disease, OR
    - Hypertension, OR
    - Chronic Obstructive Pulmonary Disease or other chronic respiratory disease
- Are 12 to 17 years of age AND HAVE
    - BMI ≥85th percentile for their age and gender based on CDC growth charts, OR
    - Sickle cell disease, OR
    - Congenital or acquired heart disease, OR
    - Neurodevelopmental disorders (e.g., cerebral palsy), OR
    - A medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19), OR
    - Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

Bamlanivimab 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 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 bamlanivimab 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 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 administered to you as part of the effort to treat your COVID-19 illness.

Is this an approved therapy?
Bamlanivimab 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 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 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. Possible side effects associated with the administration of Bamlanivimab 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 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?
We do not know if Bamlanivimab 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, 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. 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
By signing this informed consent document, I am agreeing to receive a transfusion of Bamlanivimab in conjunction with my treatment 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 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 of mild to moderate COVID-19. Bamlanivimab is NOT approved by the FDA. My physician has further explained to me the significant known and potential risks and benefits of Bamlanivimab, and the extent to which such risks and benefits are unknown. My physician has also informed me of alternatives to receiving Bamlanivimab.

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 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 fully and adequately explained to me and that by signing below, I acknowledge and consent to the administration of Bamlanivimab 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 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. ***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) 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 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 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 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, 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 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 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.
A patient is considered "high-risk" if they meet at least one of the following criteria:

- Have a body mass index (BMI) of ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age AND HAVE
    - Cardiovascular disease, OR
    - Hypertension, OR
    - Chronic Obstructive Pulmonary Disease or other chronic respiratory disease
- Are 12 to 17 years of age AND HAVE
    - BMI ≥85th percentile for their age and gender based on CDC growth charts, OR
    - Sickle cell disease, OR
    - Congenital or acquired heart disease, OR
    - Neurodevelopmental disorders (e.g., cerebral palsy), OR

- A medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19), OR
- Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

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 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 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 1200 mg/1200 mg dose of medication will be given in this infusion. Additional infusions of Casirivimab and imdevimab 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 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 a transfusion of casirivimab and imdevimab in conjunction with my treatment 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 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

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 https://www.fda.gov/media/143604/download

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF CASIRIVIMAB AND IMDEVIMAB FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called **casirivimab** and **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 casirivimab and imdevimab, which you may receive.

Receiving casirivimab and imdevimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about casirivimab and imdevimab. Talk to your healthcare provider if you have questions. It is your choice to receive casirivimab and imdevimab 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 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 CASIRIVIMAB AND IMDEVIMAB?
Casirivimab and imdevimab are 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. Casirivimab and imdevimab are investigational because they are still being studied. There is limited information known about the safety and effectiveness of using casirivimab and imdevimab to treat people with COVID-19.

The FDA has authorized the emergency use of casirivimab and imdevimab for the treatment of COVID-19 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 CASIRIVIMAB AND 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 CASIRIVIMAB AND IMDEVIMAB?
• Casirivimab and imdevimab are two investigational medicines given together as a single intravenous infusion (through a vein) for at least 1 hour.
• You will receive one dose of casirivimab and imdevimab by intravenous infusion.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF CASIRIVIMAB AND IMDEVIMAB?
Possible side effects of casirivimab and imdevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion with casirivimab and 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 casirivimab and imdevimab. Not a lot of people have been given casirivimab and imdevimab. Serious and unexpected side effects may happen. Casirivimab and imdevimab are still being studied so it is possible that all of the risks are not known at this time.
It is possible that casirivimab and imdevimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, casirivimab and 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 casirivimab and 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 casirivimab and imdevimab. Should you decide not to receive casirivimab and imdevimab 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 casirivimab and imdevimab. For a mother and unborn baby, the benefit of receiving casirivimab and 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 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.REGENCOV2.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 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.

Casirivimab and 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.

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