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

* In the event of medication shortage or FDA guidance change a different monoclonal antibody may automatically be substituted per P&T approval unless indicated on the order.

**Patient Consent for Casirivimab and imdevimab is located on pages 4-6 of this document.**

Patient FDA Fact Sheets

* Casirivimab and imdevimab pages 7-10

Upon reviewing FACT sheet and consent with patient, return order pages (2-3) and **signed** consent [(4-6) Must be signed by patient and provider prior to fax]. **Please also send a current clinic note and demographics.**

*The US government, in coordination with Eli Lilly, has stopped the distribution of bamlanivimab alone as of March 24, 2021 in response to the sustained increase in SARS-CoV-2 viral variants in the United States that are resistant to bamlanivimab administered alone, and the availability of other authorized monoclonal antibody therapies that are expected to retain activity to these variants.*

*On June 25th, 2021 the FDA halted distribution of the bamlanivimab and etesevimab due to variant emergence.*

### 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/portOther:  |
| **Vital Signs** | Per unit protocol | Other:  |
| **Consent** | Signed consent to accompany this order |
| **Medication Orders** (include drug, dose, route, frequency, duration):**Casirivimab and imdevimab** are used under an Emergency Use Authorization (EUA). The EUA is for the use of the unapproved product **Casirivimab and 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.
* **For post-exposure prophylaxis for individuals who are:**
	+ Not fully vaccinated **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, people with immunocompromising conditions, including those taking immunosuppressive medications)
	+ **And** who meet close contact criteria per Centers for Disease Control and Prevention meaning they have been exposed to an individual infected with SARS-CoV-2 (laboratory-confirmed or a [clinically](https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html) 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)

**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
* Hospitalized patient
* 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

**Inclusion criteria*** Age ≥65 years of age)
* 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)](http://www.cdc.gov/growthcharts/clinical_charts.htm%29)
* 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))
* Immunosuppressive disease or immunosuppressive treatment
 |

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: 8-2-21

***In the event of medication shortage or FDA guidance change a different monoclonal antibody may automatically be substituted per P&T approval unless indicated below.***

***Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment (e.g. >24 hour delay due to lack of infusion appointments, difficulty in returning for infusion appointment).***

**Casirivimab 600mg + imdevimab 600mg by subcutaneous injection**

* + Allow vials to equilibrate to room temperature
	+ Withdraw 2.5 mL of solution per syringe into 4 separate syringes
	+ Replace the 21-gauge transfer needles with 25-or 27-gauge needles for subQ injection
	+ Administer via subQ injection consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches around the navel; avoid the waistline
	+ Monitor patient at least 1 hour after injection.

Give 30 minutes prior to infusion/injection. *There is no recommendation that pre-medications are required with monoclonal antibodies.*

* 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 or IM 125 mg once OR

Infusion or injection-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 or injection-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.

In the event that an infusion or injection-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 or IM 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

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: 8-2-21

**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 or have been exposed to COVID-19. 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 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.c](http://www.cdc.gov/growthcharts/clinical_charts.htm%29)d[c.gov/growthcharts/clinical\_charts.htm)](http://www.cdc.gov/growthcharts/clinical_charts.htm%29)
* 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 (and possibly preventing) 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 600 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](http://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 for mild to moderate COVID-19 disease or post-exposure prophylaxis to COVID-19. 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

**FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COVTM**

**(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**](http://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html%2Cor)
* 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-](http://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](http://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](http://www.REGENCOV.com/)
* Visit https:/[/www.covid19treatmentguidelines.nih.gov/](http://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).

Manufactured by:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707

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