Stony Brook Cancer Center

Monoclonal Antibody (mAb) Infusion for COVID+ Patients

Instructions & Forms

Questions

- **SCHEDULING AND ADMINISTRATIVE QUESTIONS**:
  PLEASE CALL CAROLYN OTTAKA AT 631-216-2767 OR CELL: 631-495-5059

- **CLINICAL QUESTIONS ABOUT THE ANTIBODY THERAPY**:
  PLEASE CALL 631-444-1099 AND ASK FOR THE ANTIMICROBIAL STEWARDSHIP PHYSICIAN FOR COVID ANTIBODIES

FAQ for ordering MDs

What are the COVID monoclonal antibodies (mAbs)?

These are manufactured antibodies that target the spike protein of SARS-CoV2. Attacking the spike protein can block viral entry into human cells. There are currently two agents that have received FDA emergency use authorization (EUA): (1) casirivimab-imdevimab and (2) sotrovimab. Stony Brook Medicine is currently offering **casirivimab-imdevimab**.

How efficacious are these mAbs?

Casirivimab-imdevimab has demonstrated in clinical trials to reduce symptoms and as well as hospitalizations and emergency room visits by approximately 70% when given early in the course of the disease. In the casirivimab-imdevimab trial, there was a reduction in COVID-19 related hospitalizations (3% vs. 9% in the placebo). Casirivimab-imdevimab has also been shown to decrease the risk of symptomatic disease when given to household contacts of persons infected with SARS-CoV2 by 81%.

Who should get the COVID mAbs?

Casirivimab-imdevimab received FDA EUAs for the treatment of the following:

1. High risk (see below) persons age 12 and above who weigh at least 40kg with mild-to-moderate COVID-19 disease and are at risk for progression to more severe disease or hospitalization. Persons should have a positive COVID test (either PCR or rapid antigen testing). While the FDA has approved the agents for use in persons with symptoms for less than 10 days, clinical trials have shown the most benefit when given earlier in the disease course –within 3 days of symptom onset.

2. Postexposure prophylaxis in close contacts of persons with COVID-19 with high risk factors for progression to severe disease **and** who are not fully vaccinated against SARS-CoV2 **or** who are vaccinated but are not expected to mount an adequate response to complete SARS-CoV2 vaccination (i.e. persons on certain immunosuppressive medications)

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:

- Age ≥65 years of age
- Obesity or being overweight (for example, adults with 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 (i.e. HIV, cancer, organ transplant)
- 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))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of COVID mAb therapy under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extraprecautions/people-with-medical-conditions.html.

Healthcare providers should consider the benefit-risk for an individual patient and Infectious Diseases consultation should be considered for persons not fitting the above definitions.

Casirivimab-imdevimab is **not** approved for use in the following:

- Persons hospitalized due to COVID-19
- Persons on oxygen therapy due to COVID-19
- Persons who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

No dosage adjustments are needed based on age, weight, gender, or underlying kidney or liver disease.

Except for the COVID vaccine (see below), there are no known drug interactions involving these mAbs.

If my patient does not fit the above criteria, can she get a COVID mAb treatment at Stony Brook?

No. We are following the FDA EUA criteria as outlined above. Consultation with Infectious Diseases is recommended if there is question of whether a patient meets with EUA criteria.

What if my patient is pregnant?

The FDA has expanded the EUA to include pregnant women as a group at high risk of progression to severe disease.

What are the side effects to these mAbs?

Casirivimab-imdevimab has been found to be very safe. Infusion reactions, allergic reactions, and anaphylaxis have been reported. Patients have also reported fever, nausea, and headache. Because of these potential side effects, patients are monitored for one hour are the infusion. The site will be prepared with medications to treat hypersensitivity reactions if they occur.

Are the mAbs effective against the SARS-CoV2 variants of concern (i.e. delta)?

In vitro data suggests that casirivimab-imdevimab will be effective against the known variants of concern, including the delta variant.

If my patient gets a mAb, can they also get other COVID related therapies (i.e. remdesivir, dexamethasone) later?

Yes. Getting a mAb does not exclude one from getting any of the FDA authorized therapies for COVID-19.

If my patient gets a mAb, can they also get the COVID vaccine?

There is a risk of interference with the mAbs and the vaccine. It is recommended that persons who receive either casirivimab-imdevimab wait at least 90 days from the infusion before getting a COVID vaccine.

If my patient had a COVID vaccine, can they get a mAb?

Yes. Prior receipt of a COVID vaccine does not exclude one from getting a mAb as long as she meets the use criteria.

I am still not sure if my patient should get a mAb. What can I do?

Stony Brook Infectious Diseases can provide a telehealth consultation for your patient to help determine eligibility.

Please call the Scheduling number in the box below for this to be arranged.

How does my patient get a COVID mAb at Stony Brook?
Please use the 3 required forms (checklist, orders and consent) contained in this package.

QUESTIONS?

SCHEDULING & ADMINISTRATIVE QUESTIONS: *PLEASE CALL CAROLYN OTTAKA 631-216-2767 OR CELL 631-495-5059*
CLINICAL QUESTIONS*:* *PLEASE CALL 631-444-1099 AND ASK FOR THE ANTIMICROBIAL STEWARDSHIP PHYSICIAN FOR COVID ANTIBODIES*

Stony Brook Cancer Center

INSTRUCTIONS
How to Order Monoclonal Antibody Infusion Therapy for COVID+ Patients

1. **PATIENTS IDENTIFIED BY SBUH PROVIDERS:**

Please complete:

   a. COVID-19 Monoclonal Antibody Administration Checklist *(REQUIRED)*
   b. COVID+ Monoclonal Antibody order form *(REQUIRED)*
   c. Hypersensitivity order form (*REQUIRED)*
   d. Monoclonal Antibody consent form *(REQUIRED - includes example for phone consents)*

Fax to: "ATTENTION: COVID INFUSION" to 631-216-2944.

2. **PRE-VISIT INSURANCE ELIGIBILITY AND AUTHORIZATION**: Stony Brook Cancer Center (SBCC) Authorization Team will obtain all necessary approvals, as appropriate.

3. **SCHEDULING:** The SBCC scheduler will contact the patient and provide specific instructions and directions to the ACP (rear) entrance. Patients will be scheduled immediately, between 10:00AM and 5:00PM, Monday - Friday.

4. **REGISTRATION:** The SBCC scheduler will inform Patient Access to perform pre-registration of the encounter. On- site arrival and check-in will be remote and touchless. Patients will be provided with instructions.

QUESTIONS

- ***SCHEDULING AND ADMINISTRATIVE QUESTIONS:*** *PLEASE CALL CAROLYN OTTAKA AT 631-216-2767 OR CELL 631-495-5059*
- ***CLINICAL QUESTIONS ABOUT THE ANTIBODY THERAPY:*** *PLEASE CALL 631-444-1099 AND ASK FOR THE ANTIMICROBIAL STEWARDSHIP PHYSICIAN FOR COVID ANTIBODIES*

COVID-19 MONOCLONAL ANTIBODY ADMINISTRATION CHECKLIST
(Casirivimab-Imdevimab)

Name of Patient:		**MRN:**
Location of patient:		
ED	**ACP**	**Other: Home**

COMPLETE ALL FIELDS BEFORE ORDERING:

A. Patient Vaccination Status

☐ Not Fully Vaccinated ☐ Pfizer ☐ Moderna ☐ Johnson&Johnson

B. INDICATION FOR USE (Complete the required information in one column):

☐ **Treatment of Mild-moderate COVID-19** **Date of first symptoms:** Click or tap to enter a date. **Date of positive COVID test:** Click or tap to enter a date.	☐ **Postexposure prophylaxis for close contact to person with COVID-19** ***AND*** ☐ **Has not been fully vaccinated against SARS-CoV2** ***OR*** ☐ **Immunocompromised condition**

C. Patient Risk Factors (Please check all that apply):

☐ **Patient must be at least 12 years of age *and* weight over 40 kg**

Patients must meet at least ONE of the following criteria. Please indicate which of the criteria the patient meets: *(MUST BE COMPLETED)*

☐ Age ≥65 years of age
☐ Obesity or being overweight (for example, adults with 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
☐ Sickle cell disease
☐ Neurodevelopmental disorders (for example, cerebral palsy)
☐ Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))

☐ Other: _____

DO NOT ORDER MONOCLONAL AB IF:

- Patient requires supplemental oxygen due to COVID-19 infection
- Patient required an increase in baseline oxygen flow rate due to COVID-19 in patients on chronic supplemental oxygen due to underlying non-COVID-19 co-morbidity

D. Ordering Provider:

Name of ordering physician: _____ *(please print)*

Cell: _____

MUST BE COMPLETED

IMPORTANT:

ORDERS FOR OUTPATIENT INFUSIONS (NON- ED):

To schedule: Please fax all completed forms: "ATTENTION: COVID INFUSION" to 631-216-2944**.**

For scheduling questions: Please call Carolyn Ottaka (office 631-216-2767 or cell 631-495-5059) or Barbara McByrne (cell 631-459-1234).

For clinical questions: Please call 631-444-1099 and ask for the Antimicrobial Stewardship Physician for COVID antibodies.

ORDERS FROM THE EMERGENCY DEPARTMENT: You must call the pharmacy (444-2680) to alert them that you are sending a checklist to order Casirivimab-Imdevimab. Then this checklist (up to this point) must be sent to Pharmacy at **SBUH_Pharmacy_Leadership@stonybrookmedicine.edu** to confirm drug availability.

*** PH2C026 ***
PHYSICIAN'S ORDER SHEET

Stony Brook Medicine

Patient Label here

Date	Time	ORDERS: **Must** include physician's signature and ID#	Transcriber's Initials/ID#
		Name: DOB: Allergies: MR #: DX: **COVID INFECTION U07.1**	
		Wt:___Kg Ht:____cm Provider: please check preference of drug for your Patient. The Pharmacy will auto substitute upon availability. Access PIV/CVAD pre-Treatment as per Policy. ☒ Casirivimab 600 mg and Imdevimab 600 mg to be administered together as a single IV infusion for a combined 1200 mg IV in 150 ml NS. Infuse over 30 Min. Use 0.2-micron polyethersulfone (PES) filter for infusion Post-treatment: Observation Time: 60 min. post Infusion DC IV/CVAD access post observation time as per policy Note- please see hypersensitivity orders separately _____/_____ MD signature ID Date/Time	

Patient Name:

DOB:

MRN:

Stony Brook Medicine

ADULT MANAGEMENT OF HYPERSENSITIVITY REACTIONS

ORDERS: Must include physician's signature and ID# STAT ORDERS MUST BE COMMUNICATED TO NURSE	Trans. Init/ID#
ALLERGIES:	
DATE/TIME | **Patient weight (KGS):**	
The following are signs and symptoms of hypersensitivity: a) Uneasiness or agitation b) Tightness in the chest c) SOB, with or without wheezing d) Strider, cough e) Hypotension f) Urticaria (Hives) or rash g) Pruritus (localized or generalized itching) h) Periorbital or Facial edema, i) Facial flushing j) Lightheadedness or dizziness k) Sudden onset of back pain l) Tachycardia/bradycardia	
Reminder: Symptoms of hypersensitivity may occur hours after initial reaction. Hospitalization for up to 24 hours afterward should be considered for patients experiencing severe hypersensitivity reactions.	
NURSING: Note: Document all treatments and response in medical record. Mark chart and update EMR with ALLERGY information. Follow-up phone call the next day for outpatients discharged from clinic	
0 STOP THE INFUSION IMMEDIATELY	
0 Stay with patient, ask other staff to notify MD/LIP	
0 Obtain oxygen saturation with pulse oximetry	
0 Monitor vital signs Q 2 min until stable then Q 5 min for 30 minutes, then Q 15 minutes x 2	
0 Maintain airway, monitor patient for respiratory distress. Administer Oxygen if necessary at 2-4 liters per min	
0 Place patient in supine position if possible	
IF SYMPTOMS PERSIT or WORSEN:	
0 Administer emergency meds ordered below, as needed (available in pyxis on override)	
IV FLUIDS: D 0.9% sodium chloride to infuse at ___ mUhr	

THE **FOLLOWING MEDICATIONS** SHOULD **BE ADMINISTERED AT** THE **DISCRETION OF** THE **LICENSED INDEPENDENT PROVIDER MONITORING** THE **PATIENT.**

Check all that are not contraindicated:	**LIP**	**RN**
☐ Hydrocortisone100 mg IV Push X 1 prn for hypersensitivity reaction		
D Diphenhydramine 50 mg IV Push (slowly) X 1 prn for hypersensitivity reaction		
D Famotidine 20 mg IVPS X 1prn for hypersensitivity reaction		
☐ Dexamethasone (DECADRON) 20 mg IVPB X 1prn for hypersensitivity reaction		
D EPINEPHrine (1:1000 concentration)0.3 mg subcutaneous X 1 prn - may repeat every 5 minutes if necessary for a total 3 doses		
For Outpatients: IF SYMPTOMS PERSIST or WORSEN or Epinephrine is given: Call EMS (911		
ADDITIONAL ORDERS:		
|		
|		

MD/LIP/ Signature:	**ID#:**	**Date:**	**Time:**
Nurse Signature:	ID#:	**Date:**	**Time:**

TO BE SIGNED BY LICENSED INDEPENDENT PROVIDER MONITORING THE PATIENT IF EMERGENCY DRUGS ARE GIVEN:

MD/LIP/ Signature:	**ID#:**	**Date:**	**Time:**
Nurse Signature:	**ID#:**	**Date:**	**Time:**

SCAN TO PHARMACY AND PLACE IN PATIENT CHART

PH2C459 (3/13)

H L 2 C 4 2 3

Stony Brook Medicine
Stony Brook, NY 11794

Patient Name:

MRN #

DOB:

CONSENT TO CHEMOTHERAPY AND/OR BIOTHERAPY

I understand that I have a medical condition called COVID 19 INFECTION

I consent to Chemotherapy and/or Biotherapy with the following drugs: MONOCLONAL ANTIBODY APPROVE FOR

I understand that the purpose of this treatment is to: REDUCE SEVERITY OF COVID 19 INFECTION & COMPLICATIONS

The plan for my course of treatment is for 1 cycles or doses of chemotherapy and/or biotherapy, with each cycle given approximately every 1 days.

I have been advised that this treatment may have potential benefits, risks or side effects. I have been advised of the likelihood of achieving my goals and any potential problems that may occur during my recuperation.

The risks or side effects may include, but are not limited to: ALLERGIC REACTIONS, HYPERSENSITIVTY, FEVER, CHILLS, NAUSA, HEADACHE, WHEEZING, SWELLING OF LIPS, RASH, HIVES, DIZZINESS, PAIN AT INFUSION SITE.

I have also been advised of the alternatives to this treatment and the risks, side effects and benefits related to the alternatives.

I understand that I have received no guarantees about the benefits or results of this treatment. I have read this entire document and understand it. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction.
I impose no specific limitations or restrictions unless written below:

X			
Signature of Patient, Parent Guardian, Health Care Agent or other Representative of Patient	Relationship (if other than Patient)	Time	Date
X			
Signature of Witness	Title / Relationship	Time	Date

☐ An interpreter or special assistance was used to obtain consent

Name of Interpreter _____ ID as applicable _____

I verify that I have explained the procedure, relevant risks, benefits, alternatives, benefits and side effects related to the alternatives, including possible results of not receiving care, treatment and services.

X			
Signature of Practitioner	ID#	Time	Date

HL2C423 (2/16)

NAME:

DOB:

MRN:

HL2C594

CONSENTIMIENTO PARA QUIMIOTERAPIA Y/O BIOTERAPIA

Comprendo que tengo una condición médica llamada: _____
INFECCIÓN DE COVID-19

Doy mi autorización para recibir quimioterapia y/o bioterapia con los siguientes medicamentos: _____
ANTICUERPOS MONOCLONALES (monoclonal antibodies)

Comprendo que el objetivo de este tratamiento es: _____
REDUCIR LA SEVERIDAD Y RIESGO DE COMPLICACIONES DE LA INFECCIÓN DE COVID-19

El plan de mi curso de tratamiento consiste en **1** ciclos o dosis de quimioterapia y/o bioterapia. Cada ciclo se dará aproximadamente cada **1** días.

Se me ha informado que este tratamiento puede tener posibles beneficios, riesgos o efectos secundarios. Se me ha informado sobre la probabilidad de cumplir mis objetivos y sobre los posibles problemas que pueden ocurrir durante la recuperación.

Los posibles riesgos o efectos secundarios incluyen, pero no se limitan a: **REACCIONES ALÉRGICAS, HIPERSENSIBILIDAD, FIEBRE, ESCALOFRÍOS, NAUSEA, DOLOR DE CABEZA, SIBILANCIA, INCHAZÓN DE LABIOS, RONCHAS, URTICARIA, MAREO, DOLOR EN EL AREA DE LA INFUSIÓN**

También se me ha informado sobre las alternativas a este tratamiento al igual que los posibles riesgos, efectos secundarios y beneficios de estas alternativas.

Entiendo que no he recibido ninguna garantía sobre los beneficios o resultados de este tratamiento. He leído todo este documento y entiendo su contenido. Se me ha dado la oportunidad de hacer preguntas y he recibido respuestas satisfactorias.

No impongo ninguna limitación ni restricción específica salvo lo que se indique a continuación:

X

Firma del paciente, padre/madre guardián, agente de cuidados médicos, u otro representante del paciente	Relación (si quien firma no es el paciente)	Hora	Fecha

X

Firma del testigo	Título/relación	Hora	Fecha

☐ Se han utilizado los servicios de un intérprete o asistencia especial para obtener el consentimiento

_____ ID conforme corresponda _____
Nombre del intérprete

Confirmo que he explicado el procedimiento y los posibles riesgos, beneficios y alternativas del mismo, al igual que los riesgos y beneficios de las alternativas, incluyendo los resultados posibles si se toma la opción de no recibir cuidado/tratamiento y/o servicios médicos.

X

Firma del profesional	N.º de ID	Hora	Fecha

HL2C594 (5118)

HL2C423

Stony Brook Medicine
Stony Brook, NY 11794

Patient Name:

MRN #

DOB:

CONSENT TO CHEMOTHERAPY AND/OR BIOTHERAPY

I understand that I have a medical condition called COVID 19 INFECTION

I consent to Chemotherapy and/or Biotherapy with the following drugs: MONOCLONAL ANTIBODY APPROVE FOR

I understand that the purpose of this treatment is to: REDUCE SEVERITY OF COVID 19 INFECTION & COMPLICATIONS

The plan for my course of treatment is for 1 cycles or doses of chemotherapy and/or biotherapy, with each cycle given approximately every 1 days.

I have been advised that this treatment may have potential benefits, risks or side effects. I have been advised of the likelihood of achieving my goals and any potential problems that may occur during my recuperation.

The risks or side effects may include, but are not limited to: ALLERGIC REACTIONS, HYPERSENSITIVTY, FEVER, CHILLS, NAUSA, HEADACHE, WHEEZING, SWELLING OF LIPS, RASH, HIVES, DIZZINESS, PAIN AT INFUSION SITE.

I have also been advised of the alternatives to this treatment and the risks, side effects and benefits related to the alternatives.

I understand that I have received no guarantees about the benefits or results of this treatment. I have read this entire document and understand it. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction.
I impose no specific limitations or restrictions unless written below:

Consent discussed by: _____ (MD) via phone with _____ (Patient name, Health Care Agent or other Representative of Patient)

X _____	_____	_____	_____
Signature of Patient, Parent Guardian, Health Care Agent or other Representative of Patient	Relationship (if other than Patient)	Time	Date
X _____	_____	_____	_____
Signature of Witness	Title / Relationship	Time	Date

☐ An interpreter or special assistance was used to obtain consent

_____ ID as applicable _____
Name of Interpreter

I verify that I have explained the procedure, relevant risks, benefits, alternatives, benefits and side effects related to the alternatives, including possible results of not receiving care, treatment and services.

X _____	_____	_____	_____
Signature of Practitioner	ID#	Time	Date

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

You are being given a medicine called **REGEN-COV (casirivimab-imdevimab)** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV, which you may receive.

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. 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, 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 COVID19.

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-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:
  - 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**,
  - 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, 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 prevent COVID-19 in 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-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.

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
• 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 REGEN-COV (casirivimab-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 REGENCOV 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-imdevimab)?
Possible side effects of REGEN-COV are:
• Allergic reactions. Allergic reactions can happen during and after infusion with REGEN-COV. 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, dizziness and sweating. These reactions may be severe or life threatening.
• Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion, 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. 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-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. 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 treating pregnant women or breastfeeding mothers with REGEN-COV (casirivimab-imdevimab). For a mother and unborn baby, the benefit of receiving REGEN-COV 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 REGEN-COV (casirivimab-imdevimab)?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

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-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 or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment

of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for 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:
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