Wayne Memorial Hospital
Honesdale, PA 18431

* P H Y O R D E R *

Dangerous Abbreviations DO NOT USE		
AU	qd	Od
MS	QD	OD
MSO4	QOD	U
MgSo4	SC	IU

PHYSICIAN'S ORDERS
Casirivimab and Imdevimab Treatment – Combined IV and/or Subcutaneous
(REGN10933 and REGN10987 for COVID-19 Outpatient Use Only)

ALLERGIES	Height	Weight
	Date & Time:	

Instructions For **Casirivimab and Imdevimab** Prescribing

1. Patient must have a positive COVID-19 test. **Medication should only be given within 10 days of symptom onset.** Provider may repeat COVID test using a rapid test if concerned about previous results. No specific time frame is recommended for positive COVID testing, however it should be a recent test (preferably within the last week).
2. Patient must have Mild to Moderate symptoms and meet at least one high risk criteria. The patient cannot be on oxygen unless it is chronic use at baseline settings.
3. The ***physician*** must explain the risks and benefits of treatment and obtain consent. Consent over the phone is acceptable if witnessed. Consent is attached.
4. If possible the patient should receive the patient information from the prescriber at the time of the discussion. If this is not possible, review content with the patient. They patient will receive a copy at the infusion site. Patient information is attached.
5. **Complete the prescription.** The prescription **must be completely filled out** or it will be returned to the prescriber, possibly causing the patient to miss the treatment window! The prescription form is attached.
6. Fax the completed prescription and the consent form to the number at the bottom of the form.
7. Hospital will contact the patient if prescheduling infusion.
8. The patient should be advised to expect to spend 3 to 4 hours at our infusion site.

****CONSENT REQUIRED****

DOB:_____ Preferred Contact Number:_____
(Must be at least 12 years old)

Alternate Contact Number:_____

Date of (+) Positive COVID Test: _____
Date of Symptom Onset: _____(must be within 10 days)

Weight Over 40KG (88 lbs): ☐ Yes ☐ No (Please Check One)

Symptoms: ☐ Mild ☐ Moderate (Please Check One)

Affix Patient Label

Or patient name/DOB

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Please Check All That Apply

- ☐ Age Greater Than or Equal To 18 with BMI Greater Than or Equal to 25
- ☐ Ages 12-17 and Have BMI Greater Than 85 Percentile For Age/Gender
- ☐ Pregnancy
- ☐ Chronic Kidney Disease
- ☐ Diabetes
- ☐ Immunosuppressive disease or Immunosuppressive treatment (Please list:_____)
- ☐ Cardiovascular disease (including congenital heart disease) or hypertension
- ☐ Chronic lung diseases (for example, COPD, asthma [moderate to severe], interstitial lung disease, cystic fibrosis, 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 abnormalities)
- ☐ Having a medical-related technological dependence (for example, tracheostomy, gastronomy, or positive pressure ventilation [not related to COVID-19])
- ☐ Other medical conditions or factors (for example, race or ethnicity) that may place an individual at a high risk for progression to severe COVID-19 (Please list: _____)

****PRESCRIPTION****

☐ Casirivimab 600 mg and imdevimab 600 mg. **IV Infusion** over 1 hour x 1 Dose

		Instructions: 1. Remove medication vial from refrigerator 20 minutes before mixing.
		2. Withdraw 10 mL of the **Casirivimab/Imdevimab combination** from the single vial into a 10 mL syringe.
		3. Inject the 10 mL of the Casirivimab/Imdevimab solution (600mg/600mg) into 250ml of 0.9% NSS under aseptic technique.
		4. Label the IV bag with the contents and amounts.
		5. ***DO NOT SHAKE*** vial or IV bag with medication in it to mix. Gently invert the mixed solution bag 10 times to properly mix the medication and fluid together.
		6. Attach a 0.2 micron filter to the infusion set if tubing is not filtered already.
		7. Administer mixed medication **immediately** by infusing at a rate of 260 ml/hour via infusion pump.
		8. Flush the line with 0.9% Sodium Chloride solution post-infusion to ensure full delivery of dose.
		9. Monitor patient during infusion and 1 hour post completion for signs and symptoms of an allergic or anaphylactic reaction.
		10. Follow anaphylaxis protocol for allergic reaction.

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☐ Casirivimab 600 mg and imdevimab 600 mg. **Subcutaneous injection** x 1 dose (four injections of 2.5 mL)		
		Instructions: 1. Remove medication vial from refrigerator 20 minutes before administering.
		2. Withdraw 2.5 mL of the **Casirivimab/Imdevimab combination** from the single vial into four 3 mL syringes.
		3. Administer drawn up medication **immediately** by injecting into different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of casirivimab and imdevimab.
		4. Monitor patient during infusion and 1 hour post completion for signs and symptoms of an allergic or anaphylactic reaction.
		5. Follow anaphylaxis protocol for allergic reaction.
V.O./T.O.		**Physician Name:** ☐ **Orders Read Back and Verified**
Physician Signature		**Date** **Time**
Nurse's Signature		**Date** **Time**

FAX TO 570-253-8634

Affix Patient Label

Or patient name/DOB

Wayne Memorial Hospital

* C O N S E N T *

INFORMED CONSENT
OFF LABEL MEDICATION USE FOR THE TREATMENT OF COVID19

It is very important to your doctor that you understand and consent to the treatment your doctor is rendering. You should be involved in any and all decisions concerning this treatment. Sign this form **only after you understand** the procedure, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered.

Medications (Select All To Be Prescribed):

- ☐ **Casirivimab and Imdevimab Treatment**
- ☐ Other:_____
- ☐ Other:_____

_____

I understand and agree to the off-label use of **the above selected medications** in the management of COVID19. I understand that Off-label prescribing, also known as unapproved use, is the physician practice of prescribing a drug for a purpose different from one of the indications for which the product is approved by the Food and Drug Administration (FDA).

Because there has not been sufficient testing by the FDA, my physician does not have tested information on use, dosage, and route of administration that is provided in product labeling for approved indications. Furthermore, the safety and efficacy of the unapproved use has not have been established by adequate and well-controlled clinical trials.

I am willing to accept the potential risks that my physician has discussed with me. I acknowledge that there may be other, unknown risks and that the long-term effects and risks of the off label use of the above medications are not known.

I also understand that I have other medical alternatives to this off label use. With this knowledge of the potential risks, benefits, alternatives, and complications, I request that my doctor proceed with the off-label prescription the above selected medications.

I also acknowledge that the doctor has reviewed the use of this medication with me in detail, and answered all of my questions on the subject of the use of this medication.

By signing below, I have had an opportunity to ask the doctor all questions concerning risks, alternatives, and risks of those alternatives.

Date	Time	Signature of Patient/Authorized Rep.	Relationship of Authorized Rep.
_____	_____	_____	_____

Affix Patient Label

I:\FormsCommitteeApproved\CONSENTS\INFORMED CONSENTS\Informed Consent Off Label Rx Use To Treat Covid 19.docx FINAL: 3/26/2020; Rev. 1/15/21; 1/28/21, 4/23/21

INFORMED CONSENT
OFF LABEL MEDICATION USE FOR THE TREATMENT OF COVID19

- ☐ The Patient/Authorized Representative has read this form or had it read to him/her.
- ☐ The Patient/Authorized Representative states that he/she understands this information
- ☐ The Patient/Authorized Representative has no further questions.

☐ Verbal consent was given by the Patient/Authorized Representative **(requires second Witness Signature)**

Date	Time	Signature of Witness
Date	Time	Signature of Witness

CERTIFICATION OF PHYSICIAN:

I hereby certify that the facts, risks, the risks associated with the alternatives of the procedure(s) described in this form have been discussed with the individual granting consent.

Date	Time	Signature of Physician

IMPLIED CONSENT

Implied consent can be assumed when immediate treatment is required to preserve the life of a patient or to prevent impairment of the patient's health; and it is impossible to obtain the consent of the patient or their authorized representative. Unconscious patients are presumed under law to approve treatment that appears to be necessary.

Date	Time	Signature of Physician
Date	Time	Signature of Witness

Affix Patient Label

I:\FormsCommitteeApproved\CONSENTS\INFORMED CONSENTS\Informed Consent Off Label Rx Use To Treat Covid 19.docx FINAL: 3/26/2020; Rev. 1/15/21; 1/28/21, 4/23/21

Discharge Information and Fact Sheet for REGEN-COVTM (casirivimab with imdevimab)
FOR CORONAVIRUS DISEASE 2019 (COVID-19)

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

You are being given a medicine called REGEN-COV (casirivimab with 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. 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, 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 REGEN-COV (casirivimab with imdevimab)? REGEN-COV is an investigational medicine 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. 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. 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.

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
- 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 with imdevimab)? REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together as a single intravenous infusion

(through a vein). You will receive one dose of REGEN-COV by intravenous infusion. The infusion will take about an hour or longer. Your healthcare provider will determine the duration of your infusion but you should plan on spending a total of 4 hours at the facility.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab with 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. 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 with 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 IF I AM PREGNANT OR BREASTFEEDING? There is limited experience treating pregnant women or breastfeeding mothers with REGEN-COV (casirivimab with 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 with 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.

Discharge Information and Fact Sheet for REGEN-COVTM (casirivimab with imdevimab)
FOR CORONAVIRUS DISEASE 2019 (COVID-19)

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 with 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.

PLEASE REFER TO ANY ADDITONAL DISCHARGE INSTRUCTIONS PROVDIED FOR FURTHER INFORMATION ON FOLLOW UP CARE AFTER INFUSION.

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