Patient Consent for Treatment Form

NAME OF DRUGS: **Casirivimab and Imdevimab (REGENCOV™)**

SITE OF TREATMENT: Applegate Valley Family Medicine, LLC

PHONE NUMBER: (541) 862-2836

Your doctor or Nurse Pracitioner has recommended you be treated with two drugs named casirivimab and imdevimab – also referred to as REGEN-COV™. You have the option to be treated with these medications, casirivimab and imdevimab SQ (subcutaneously that is, by injection under your skin). Before you decide whether you would like to be treated with these medications, your medical provider would like you to review this information. If you decide that you would like to receive this treatment, you will be asked to sign this form. A copy of this form and an FDA approved fact sheet will be given to you for your reference.

What are 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 of the Fact Sheet for Patients, Parents and Caregivers that you have received.

Casirivimab and imdevimab are two investigational medicines given together as four single injections under the skin (SQ or subcutaneously) in four different areas of the body. You will need to be observed for **at least** one hour (60 minutes) after the treatment is completed.

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, 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 under the skin may include pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the injection 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 (COVID-19). Similarly, casirivimab and imdevimab may reduce your body's immune response to a vaccine for SARS-CoV-2. You should not get a vaccine for 90 days after this treatment. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

TREATMENT PLAN

The following procedures and assessments will be performed prior to, during, and after treatment with this medication.

Assessments	Pre-dose	On Treatment	Post-dose / follow up
Medical History	**X**		
Vital signs	**X**		**X**
Physical Exam	**X**		**X**
Monitor for Adverse Reactions/Events		**X**	**X**

RISKS

There are some known risks and adverse reactions to using this medication. You will be provided with the FDA-approved fact sheet that accompanies the emergency use authorization for this medication. You will also be provided with a copy of this consent form. Talk to your medical provider about any questions or concerns you have regarding these potential risks or adverse reactions prior to starting this treatment.

MEDICAL HISTORY

You may have a greater chance of experiencing known risks/adverse reactions if you have certain medical problems or conditions. Please tell your medical provider about all of your health conditions. In particular, please mention if you have any of the following health problems:

- Any allergies
- Any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking medications, including prescription, over the counter medications, vitamins, and herbal products

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.

Your healthcare provider may talk with you about clinical trials you may be eligible to participate in.

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. Please notify the healthcare provider at Central Maine Medical Center that gave you this treatment.

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.

COSTS
The cost of the medication was incurred by the Federal government, but your insurance may be billed for administration of the medication.

YOUR PERSONAL INFORMATION
Your personal information will be protected under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended from time to time (collectively, HIPAA) as stated in the Central Maine Medical Center Consent, Use and Disclosure Statement. Some of your personal information may be retained in the Clinical Research Department for a limited period of time to optimize your individual care and in accordance with federal regulations. Your information will be made accessible to Regeneron Pharmaceuticals, Inc. as well as the FDA and other regulatory agencies that choose to review it.

Patient Statements:

- I have read this consent form, or had it read to me. I understand the risks and benefits associated with taking this medication as authorized by the FDA for emergency use and have had the opportunity to ask and have questions answered.
- I would like to pursue treatment for COVID-19 with casirivimab and imdevimab (REGEN-COV™).
- I understand that this medication has not been approved to treat COVID-19.
- I will be given a signed copy of this document for my records.
- I have received a copy of the FDA-approved Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab and imdevimab) for Coronavirus Disease 2019 (COVID-19)
- By signing this form, I am not waiving any of my legal rights.

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Patient Name

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Patient/ Caregiver/ Legally Authorized Representative Signature Date and Time

Provider Statements:

- I have reviewed the information in this form with the patient (and Legally Authorized Representative, if applicable).
- I have answered the patient's (and Legally Authorized Representative's, if applicable) questions to the best of my ability.

_____

Provider's Printed Name

_____ _____

Provider's Signature Date and Time