McLeod Health

The Choice for Medical Excellence

Casirivimab/Imdevimab (REGEN-COV®) Referral Form **DATE:_____**

Please complete & fax to the COVID Call Center at **843-777-9755** with a copy of positive COVID-19 result if available.

Patient Name: _____ **Date of Birth: _____**

Allergies: _____ **Patient Email: _____**

Contact Number (Patient/Caregiver): _____ **Preferred Location:** ☐Florence ☐Loris ☐Clarendon ☐Seacoast

Date of symptom onset (must be within the last 10 days): _____ **Date of Positive Test: _____**

Diagnosis: COVID-19 – ICD 10: U07.1

Ht: _____in **Wt: _____kg** **BMI: _____**

Indication:
Emergency Use Authorization (non-FDA approved) for treatment of mild to moderate COVID-19 illness

Verify that the patient meets the criteria below by checking the boxes:

☐ symptom onset within **less than 10 days**

☐ high risk of progressing to severe COVID-19 and/or hospitalization defined by (**check at least one**):

- ☐ ≥ 65 Years of Age (Tier1)
- ☐ ≥18 Years of Age **AND** BMI ≥ 25 (Tier 2)
- ☐ ≥18 Years of Age **AND** a high-risk condition as determined by a healthcare provider (examples may include chronic kidney disease, diabetes, immunosuppressive disease or treatment, cardiovascular disease, hypertension, chronic lung disease, sickle cell disease, neurodevelopmental disorders, ethnicity, etc.) (Tier 3)
- ☐ 12-17 Years of Age **AND** a BMI of ≥ 25 or a high risk condition as determined by a healthcare provider & facility approval (Tier 4)

Confirm that patient has received the EUA Fact Sheet for Patients and Caregivers. If hard copy cannot be provided it will be provided at the infusion site but **please check box below to confirm patient understands and has consented**.

- *"I verbally provided the patient/caregiver the information contained in the casirivimab/imdevimab fact sheet for patients and parents/caregivers including that the FDA has authorized the emergency use of this therapy for COVID-19. The patient/caregiver had the option to accept or refuse treatment. Information was provided about the significant and known potential benefits and risk and the extent to which such risks and benefits are unknown. After discussing this information with the patient/caregiver, the patient/caregiver agreed to begin treatment."*

Referring Provider Signature :_____

Provider Name & Contact Information: _____

Please note patients are scheduled based on appointment availability, drug allocation, and patient criteria including tier and symptom onset date. All requests may not be able to be accommodated. Referring provider will be notified if the patient cannot be scheduled. If you have any questions, please contact the COVID Call Center at 843-777-2919 and press 5.

8/19/2021

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

You are being given a medicine called **REGEN-COV (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 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, 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 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 and 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 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
- 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 together in the form of subcutaneous injection (medicine is injected in the tissue just under the skin). One dose will consist of 4 subcutaneous injections given in separate locations around the same time.

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 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, 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, 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 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-legal-regulatory-and-policy-framework/emergency-use-authorization 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 and 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 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.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 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 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).

REGENERON

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