Casirivimab and Imdevimab (REGEN-COV) Patient Reservation Checklist

Physicians requesting the use of Casirivimab and Imdevimab under Emergency Use Authorization (EUA) must fax the following information to the St. Clair Hospital Pharmacy Department at 412-942-1420. Each case will be reviewed per institution and FDA qualification criteria by a multidisciplinary team.

Please answer the following questions completely:

☐ Patient Name: ____________________________________________________________

☐ Physician Office Name: ____________________________________________________

☐ Prescribing Physician: ______________________________________________________

☐ Physician Office Phone Number: ________________________________

☐ Physician Office Fax Number: ______________________________________________

Please return all three of the following with this reservation checklist:

☐ SARS-CoV-2 Positive Test Copy

☐ Completed Casirivimab and Imdevimab Infusion Patient Consent Form

☐ Completed Casirivimab and Imdevimab Order Set

Failure to send the completed information above will result in the patient not being reviewed for Casirivimab and Imdevimab infusion consideration.
Physicians requesting the use of REGEN-COV (casirivimab and imdevimab) under Emergency Use Authorization (EUA) must contact clinical pharmacy specialist for patient consideration. Patient will be reviewed by a multidisciplinary team, who will provide approval or denial. The following questions must be answered by the requesting physician prior to authorization process:

**Criteria for Use:**

1. **SARS-CoV-2 Positive Test**
   a. Patient must have direct positive test

2. **Outpatient Status**
   a. Patient is not admitted and does not require hospitalization

3. **Supplemental Oxygen Status**
   a. Patient does not require oxygen supplementation above baseline status at home

4. **High Risk Status**
   a. Patient has one of the following risk factors:
      i. Age ≥ 65, BMI ≥ 25, CKD, diabetes, immunosuppressive disease, receiving immunosuppressive treatment, pregnancy, cardiovascular disease, hypertension, COPD/other respiratory disease, sickle cell disease, neurodevelopmental disorders, and medical-related technological dependence (tracheostomy, gastrostomy, or positive pressure ventilation) OR
      ii. Age 12-17 and have:
         BMI ≥ 85th percentile for their age and gender based upon CDC growth charts or any of the above risk factors

5. **Duration of Symptoms ≤ 10 days**
   a. Date of symptom onset

If approved by multidisciplinary team, patient will be scheduled and receive the following:

Premarkedication (given 30 minutes prior to infusion):

- Famotidine 20 mg IV push x 1 dose
- Acetaminophen 650 mg by mouth x 1 dose
- Diphenhydramine 25 mg IV push x 1 dose PRN infusion reaction

Casirivimab 600 mg and imdevimab 600 mg in 100 mL NSS IV piggyback with 0.2 micron PES filter over at least 30 minutes

Patient must receive casirivimab and imdevimab infusion by this date: ________________

Prescribing physician to schedule patient for follow-up appointment 24-48 hours post infusion

**Physician Signature:** __________________________ Date: __________ Time: ________
1. I authorize Dr. ___________________________ and whomever he or she may designate as assistants, to order for the above-named patient the administration of the drug REGEN-COV (casirivimab and imdevimab), which is currently authorized for emergency use by the Food & Drug Administration (FDA).

2. I understand that REGEN-COV treatment is used in cases of COVID-19. REGEN-COV is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it’s safe and effective. Because REGEN-COV is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use; however, the FDA has authorized emergency use of the drugs for use in cases of COVID-19 infection under 21 U.S.C. 360bbb-3 of the Food, Drug, and Administration Act.

3. I acknowledge that the nature, risks and consequences of the use of REGEN-COV and the possible alternatives to the treatment, including no treatment, and their nature, risks and consequences have been fully explained to me. Some of the known possible side effects of this medication include, but are not limited to, 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 can happen during and after the infusion and should be reported to the healthcare provider right away. These are not all the possible side effects. Serious and unexpected side effects may happen.

4. I acknowledge that I have received the appropriate information sheet “FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV (casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)”, that I have been given an opportunity to ask questions about the treatment and that all questions which I have asked have been answered to my satisfaction.

5. I acknowledge that there may be unforeseen complications, injury, or even death from both known and unknown causes associated with REGEN-COV administration.

6. I acknowledge that no guarantee or assurance has been made as to the result or cure that might be obtained from the treatment.

Acknowledged by Dr __________________________ Date ____________ Time ____________
(Physician Signature required)

I CERTIFY THAT I HAVE READ AND FULLY UNDERSTAND THE ABOVE STATEMENTS, THAT THE EXPLANATIONS THEREIN REFERRED TO HAVE BEEN MADE CLEAR TO ME, THAT ALL BLANKS OR STATEMENTS REQUIRING INSERTIONS OR COMPLETIONS HAVE BEEN FILLED IN, AND THAT I WISH TO GIVE THE ABOVE AUTHORIZATION AND ACKNOWLEDGEMENT.

Date ____________ Time ____________
Patient’s Signature

If this patient is unable to sign, complete the following lines:

This patient unable to sign because __________________________

Person Signing on Behalf of Patient ____________ Relationship to Patient ____________

Date ____________ Time ____________
Witness’ Signature