PATIENT IDENTIFICATION

INFORMED CONSENT

Casirivimab & Imdevimab Treatment in cases of COVID-19

I hereby certify that I have explained the risks, benefits, alternatives, and possible modes of treatment to this patient. We have jointly arrived at the decision to proceed with the administration of Casirivimab & Imdevimab which is currently authorized for emergency use by the Food & Drug Administration (FDA).

On File _____ _____ _____

Signature of Physician **Date** **Time**

I, the undersigned, hereby authorize ReNue RX pharmacists, medical providers and/or their designee to administer and/or dispense Casirivimab & Imdevimab, monoclonal antibodies for the purpose of treating COVID-19, and to perform such additional procedures as are considered necessary to monitor and care for this patient while participating in this treatment course.

- Casirivimab & Imdevimab have not been approved, but have been authorized for emergency use by FDA, to treat mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- Casirivimab & Imdevimab are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the Casirivimab & Imdevimab under Section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

I hereby certify that Dr._____ has answered all my questions and explained to me the reasons why use of the above named medications is considered desirable or necessary, its advantages and possible complications, if any, as well as possible alternative modes of treatment. Some of the known risks of these medications explained to me include, but are not limited to allergic reactions, fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of my lips, face, or throat, rash, including hives, itching, muscle aches and dizziness. These can happen during and after the infusion and should be reported to my healthcare provider right away. These are not all the possible side effects. Serious and unexpected side effects may happen.

Casirivimab & Imdevimab are still under investigation. Therefore, there may be risks, side effects, and/or long-term effects that are related to this treatment but are unknown at this time.

I have been advised of risks and possible benefits, although no guarantee or assurance has been made as to the results to be obtained.

This treatment has been carefully explained to me. Additional printed material specific to my drug therapy has been reviewed and given to me. I received and reviewed the **Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Casirivimab & Imdevimab for Coronavirus Disease 2019 (COVID-19).** This permission is based on knowledge and understanding of the elements of the therapy and an awareness of the risks, consequences, and discomforts.

I will self-isolate and use infection control measures (e.g. wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and perform frequent hand washing) according to CDC guidelines.

I understand clearly that I can stop my participation in treatment at any time and that such a discontinuation will not prejudice my future medical care.

I, the undersigned, hereby consent to proceed with the use of these medications.

_____ _____ _____
Patient / Representative Signature Date Time

_

_____
Relationship to Patient

_____ _____ _____
Witness Signature / Title Date Time

_____ _____ _____
Additional Witness or Interpreter (if needed) Date Time

__ Patient Unable to Sign Due To: _____

ReNue PHARMACY

COVID-19 Monoclonal Antibody Treatment Order Form

****COMPLETE ALL FIELDS TO AVOID TREATMENT DELAYS****

Please email completed form to info@renuerx.com or FAX:

Patient Information: Patient Name:_____DOB:_____SS#:_____

Insurance Company:_____Group ID:_____Member ID:_____

Address:_____City:_____State:_____Zip:_____

Phone:_____❑Male ❑Female Ht:_____in/cm Wt:_____lb/kg

Allergies: ❑NKDA ❑_____

Emergency Contact Name:_____Emergency Contact Phone:_____

*****Please fax with order form**: • Current medication list • Copy of insurance card

Diagnoses: ❑ COVID-19 Virus, Identified (REQUIRED) ICD-10: U07.1

Therapy should be initiated ASAP after positive test, and within 10 days of symptom onset.

Date of symptom onset:_____COVID Positive Result Date:_____

COVID vaccination status: ❑Vaccinated (date of final dose):_____❑Unvaccinated

Eligibility:

Exclusion Criteria (If patient meets any of the following, they are not eligible for treatment):

- ❑ Currently hospitalized due to COVID-19
- ❑ Requires new or increased oxygen therapy due to COVID-19

Inclusion Criteria:

- ❑ Patients must be >=12 years old (Age:_____), AND weigh >= 40 kg (Wt:_____kg), AND be at high risk for progressing to severe COVID-19 or hospitalization.

Factors which place this patient at higher risk (check all that apply):

- ❑ Older age (ie: >=65 years old) ❑ Overweight/obese (ie: BMI>25, or pediatrics >85th%)
- ❑ Pregnancy ❑ Chronic Kidney Disease ❑ Diabetes
- ❑ Immunosuppressive Disease or Treatment ❑ Cardiovascular disease or hypertension
- ❑ Chronic lung disease ❑ Sickle cell disease ❑ Neurodevelopmental disorder
- ❑ Medical-related technological dependence
- ❑ Other (please specify): _____

Medication Orders: *Pharmacist to choose brand based on availability. If you prefer to prescribe one or the other, please cross out the brand you do **not** want to prescribe (this may cause a treatment delay).

- ❑ ***Casirivimab and Imdevimab** (REGEN-COV): 600 mg / 600 mg IV x 1 dose
  Directions: Infuse IV over 20-50 minutes per manufacturer guidelines.
- ❑ ***Bamlanivimab and Etesevimab:** 700 mg / 1.4 gm IV x 1 dose
  Directions: Infuse IV over 21-60 minutes per manufacturer guidelines.
- ❑ Alteplase 2mg IV to declot central IV access per Infusion Solutions protocol as needed for occlusion.
- ❑ Flush line with D5W, 0.9% NaCl and/or Heparin 10 units/ml or 100 units/ml per Infusion Solutions protocol.
- ❑ Lidocaine 1% - up to 0.2ml intradermally PRN (may buffer with sodium bicarbonate 8.4% in 10:1 ratio).
- ❑ Infusion Reaction Management per Infusion Solutions protocol as needed.

Nursing Orders:

- ☒ RN to insert peripheral IV or access existing central catheter.
- ☒ RN to observe patient for 1 hour post-infusion.

_____ _____

Prescriber Signature *Date*

_____

Please Print Name

Infusion Solutions Use Only:

- ☐ Pt notified of EUA status & right to decline treatment
- ☐ RPh counsel offered

Initials_____Date_____