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Patient name:
Date of birth:
Patient Sticker if available - must have phone
number for follow up after infusion

I certify the par	tient/legal rep	resentative was:
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- 1) Informed that Casirivimab 600mg + Imdevimab 600mg is an unapproved drug that is authorized for use under this EUA
- 2) Instructed on risks, benefits, & alternatives to Casirivimab 600mg + Imdevimab 600mg
  - After informed decision-making, the patient puts a high value on the uncertain benefits and a low value on uncertain adverse events.
- 3) Given the "Fact Sheet for Patients, Parents and Caregivers" prior to administration, AND
- 4) The patient meets appropriate criteria for administration
  - ≥12 years of age
- ≥40kgs mild to moderate COVID-19 disease
- at high risk for progressing to severe COVID-19 and/or hospitalization
- is NOT hospitalized,
- is NOT requiring oxygen therapy due to COVID-19,
- is NOT requiring an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity
- (≤10days) Date of positive test: for COVID + Patients only Date of symptom onset OR
- Post-Exposure to COVID-19 at high risk for progression to severe COVID-19 AND who are not fully vaccinated -or- have an immunocompromising condition \*EUA for Regeneron Casirivimab/Imdevimab only\*

### QUALIFYING REASONS FOR ADMINISTRATION (must choose at least one of the following)

#### MEETS HIGH RISK CRITERIA: **Patient Selection and Treatment Initiation**

- This section provides essential information on the unapproved product, REGEN-COV (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab) supplied in individual vials to be administered together, for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death [see Limitations of Authorized Usel.
- The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:
  - [ ] Older age (for example, age ≥65 years of age)
  - [ ]Obesity or being overweight (for example, BMI >25 kg/m2 , or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical\_charts.htm)
  - [ ]Pregnancy
  - ] Chronic kidney disease
  - 1Diabetes
  - Immunosuppressive disease or immunosuppressive treatment
  - [ ]Cardiovascular disease (including congenital heart disease) or hypertension
  - [ ]Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and 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 anomalies)
  - [ ] Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))
  - [ ] Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above.
- For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019cov/need-extra-precautions/people-with-medical-conditions.html.

Physician Signature and Printed Name	Date	Time

https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf Noted: Date

Time



## COVID 19 ANTIBODY THERAPY EUA Order Sheet

Allergies:	
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Patient name:	
Date of birth:	
Patient Sticker	if available - must have phone
number f	or follow up after infusion

Healthcare providers should consider the benefit-risk for an individual patient.

REGEN-COV is not authorized for use in patients [see Limitations of Authorized Use]: • who are hospitalized due to COVID-19, OR • who require oxygen therapy due to COVID-19, OR • who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

#### ORDERS

<u>Administer:</u> As soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset. Infuse using 0.2 micron filter tubing over the prescribed time frame. Monitor patient well being for at least 1 hour. Initiate Emergency orders and call a physician if an adverse reaction occurs. See orders below.

Casirivimab 600mg + Imdevimab 600mg IV infusion - diluted in NS 100ml @ 300 mls/hr - infuse over 21 minutes or longer. Follow with a 50ml NS Flush bag.

#### Allergic Reaction Emergency Orders:

- Contact a physician immediately.
- Call a Rapid Response or Code Blue as appropriate.
- Document Adverse Drug reaction in Vigilanz pharmacy will send to FDA
- The initial management of anaphylaxis includes procurement of a stable airway, place patient in supine or in Trendelenburg's position, administer supplemental oxygen and pressors as needed

#### Signs & Symptoms:

- · Cardiovascular hypoperfusion (decreased circulation)
  - Initiate IV NS to maintain a systolic BP greater than 90 mmHg
- Respiratory Acute respiratory distress, stridor, wheezing
  - Epinephrine 1:1000. 0.3 mg IM or SQ if the patient has respiratory distress (inspiratory & expiratory wheezing, stridor and/or laryngeal edema), hypotension and/or ALOC. May repeat x 1 in 10 minutes if necessary
  - Contact a physician immediately.
  - Call a Rapid Response or Code Blue as appropriate.
  - Albuterol 2.5 mg via nebulizer over 10 minutes. May repeat as needed

If wheezing persists and BP is >90mmHg, consider adding Atrovent 0.5mg to nebulizer

- · CNS headache, dizziness, seizure
  - Headache Acetaminophen 1000mg PO
  - Dizziness Dimenhydrinate 50mg PO
  - Seizure Contact Physician immediately Lorazepam as prescribed by physician
- · GI Abd. Pain, nausea, emesis,diarrhea
  - Diphenhydramine: 50mg IV or IM
- · Skin Rash, itching, welts and/or hives
  - Diphenhydramine: 50mg IV or IM for severe itching and/or hives
  - Methylprednisolone 125mg IV x1

Physician Signature and Printed Name	Date	Time

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Time



# COVID 19 ANTIBODY THERAPY EUA Order Sheet

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NURSING PROTOCO
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Patient name: \_\_\_\_\_\_

Date of birth: \_\_\_\_\_

Patient Sticker if available - must have phone

number for follow up after infusion

- Have patient wait to enter the site until pre-scheduled time for treatment
- Ensure patient wearing a mask or face covering before entering the building
- Escort patient directly to room, limit transport and movement of the patient outside of the room
- Keep the door closed while patient in infusion room
- Medical and support personnel entering room need to wear sufficient PPE based on CDC guidelines
- Room should undergo appropriate cleaning and surface disinfection before it is returned to routine use
- Instruct patient to continue to self-isolate and use infection control measures according to CDC guidelines.(e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing)

<u>FAX ORDERS TO (5</u>	<u>80) 585-5472</u>
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Physician Signature and Printed Name Date

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Time