

COVID 19 ANTIBODY THERAPY EUA Order Sheet

Allergies: _____

Patient name: _____

Date of birth: _____

Patient Sticker if available - **must have phone number for follow up after infusion**

I certify the patient/legal representative was:

- 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 • ≥ 40 kgs • 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
 - Date of symptom onset _____ (**≤ 10 days**) Date of positive test: _____ - for COVID + Patients only
 - 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 Use].
- 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 ≥ 85 th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
 - [] Pregnancy
 - [] Chronic kidney disease
 - [] Diabetes
 - [] 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/2019-cov/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 _____

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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

Administer: 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 and infused in: **check one below**
follow infusion with 50ml NS FLUSH

NS 50ml @ 180mls/hr - minimum infusion time 20 minutes
NS 100ml @ 310mls/hr - minimum infusion time 21 minutes
NS 150ml @310mls/hr - minimum infusion time 31 minutes
NS 250ml @310mls/hr - minimum infusion time 50 minutes

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 _____

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NURSING PROTOCOL

- 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)

FAX ORDERS TO (580) 585-5472

Physician Signature and Printed Name

Date

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