REGEN-COV (casirivimab and imdevimab) Order Form

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products casirivimab/imdevimab for the treatment of mild to moderate coronavirus disease 2019 or for post-exposure prophylaxis in qualified adults and pediatric patients.

Response	Inclusion Criteria (All must apply)
❑ Yes ❑ No	Authorized for use under an EUA for treatment of 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 least 40 kg**
❑ Yes ❑ No	**Symptomatic from SARS-CoV-2 ≤ 10 days** of direct SARS-CoV-2 viral testing
❑ Yes ❑ No	Are at **high risk** for progressing to severe COVID-19 and/or hospitalization. (**must meet 1 or more; select from below**)
	OR all of the following must apply
❑ Yes ❑ No	Adult or pediatric **(> 12 years of age and weighing at least 40kg)** patient at **high risk** for progressing to severe disease or death **(must meet 1 or more criteria from below)**
❑ Yes ❑ No	**Not fully vaccinated** or who are **not expected to mount an adequate immune response** to complete SARS-CoV-2 vaccination
❑ Yes ❑ No	**Have been exposed** to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC3 3 CDC's Quarantine and Isolation **OR – who are at high risk of exposure** to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons)

High Risk Criteria	

❑ Yes ❑ No Older age (for example age ≥65 years of age)
❑ Yes ❑ No Obesity or being overweight (for example, adults with 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)
❑ Yes ❑ No Pregnancy
❑ Yes ❑ No Chronic kidney disease
❑ Yes ❑ No Diabetes
❑ Yes ❑ No Immunosuppressive disease or immunosuppressive treatment
❑ Yes ❑ No Cardiovascular disease (including congenital heart disease) or hypertension
❑ Yes ❑ No Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
❑ Yes ❑ No Sickle cell disease
❑ Yes ❑ No Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
❑ Yes ❑ No 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 monoclonal antibodies under 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-ncov/need-extra-precautions/peoplewith-medical-conditions.html . Healthcare providers should consider the benefit-risk for an individual patient.

Patient Label

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Response	Exclusion Criteria (If any are marked YES, the patient is excluded from receiving monoclonal antibody):
❑ Yes ❑ No	Hospitalized due to SARS-CoV-2
❑ Yes ❑ No	Require new oxygen therapy or an increase in oxygen therapy due to COVID -19 (it could worsen clinical outcomes for such patients)
❑ Yes ❑ No	Requires an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-**SARS-CoV-2** related comorbidity

Monoclonal Antibody Injection Order

Casirivimab/imdevimab 600 mg/600 mg (10 mL) Pharmacist to administer 2.5ml subcutaneously x 4 injections sites

Anaphylaxis prn orders: In the course of treating adverse events, the pharmacist is authorized to administer an Epipen 0.3mg by appropriate routes pending arrival of emergency medical services. The pharmacist will maintain current certification in cardiopulmonary resuscitation.

Pharmacist must don appropriate PPE as set pharmacy policy.

Patient must be observed for **anaphylactic reactions and injection related reactions** such as (but not limitedto) fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, and dizziness

Patient must remain in observation for at least 60 minutes post injection

Check the following boxes when the patient or legally authorized representative has received the following:

❑ **Verbal Consent/Fact Sheet Given:** Patient/caregiver given the Fact Sheet for Patients and Parents/ Caregivers (Fact Sheet for Patients and Parent/Caregivers (Emergency Use Authorization (EUA) Of Casirivimab/Imdevimab For COVID-19.

❑ Informed of **alternatives** to receiving casirivimab/Imdevimab and that these are **unapproved drugs** authorized by the FDA for emergency use in the treatment of COVID-19.

Note: An order for REGEN-COV (casirivimab and imdevimab) must be entered into PMR prior to drug administration.

_____ **Provider Signature**

_____/_____/_____ **Date**

_____ **AM PM** **Time**

Patient Label