



COVID-19 Monoclonal Antibody Eligibility: Treatment and Post-Exposure Prophylaxis

Purpose: Monoclonal antibodies are used to neutralize the COVID-19 virus and intended to prevent progression of disease. The U.S. Government is currently supplying REGEN-COV (casirivimab and imdevimab) for the treatment and post-exposure prophylaxis of COVID-19. The dosing is the same for both indications (casirivimab 600mg and imdevimab 600mg).

WHO IS ELIGIBLE

Adult or pediatric (≥ 12 years of age and weighing at least 40 kg) patient at **high risk** for progressing to severe disease or death.

High Risk Factors for Treatment and Post-exposure Prophylaxis (patient should have one or more high risk factors as listed below or determined by the evaluating healthcare provider):

- Older age (for example ≥ 65 years of age)
- Obesity or being overweight (for example, adults with BMI ≥ 25 , or if age 12-17, have BMI $\geq 85^{\text{th}}$ percentile for their age and gender based on [CDC growth charts](#))
- 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 abnormalities)
- 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 mAb therapy 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, visit the CDC website.

FOR COVID-19 POSITIVE PATIENTS

Treatment Dosing: Patients who are COVID positive, with mild to moderate symptoms, not hospitalized due to COVID symptoms, and not requiring oxygen or an increase in home oxygen therapy are eligible.

COVID+ test date _____ Date of symptom onset _____ (must be <10 days)

- Symptoms
- | | | |
|---|---|--|
| <input type="checkbox"/> Fever or chills | <input type="checkbox"/> Cough | <input type="checkbox"/> Shortness of breath or difficulty breathing |
| <input type="checkbox"/> Muscle or body aches | <input type="checkbox"/> Sore throat | <input type="checkbox"/> Headache |
| <input type="checkbox"/> New loss of taste or smell | <input type="checkbox"/> Congestion or runny nose | |
| <input type="checkbox"/> Nausea or vomiting | <input type="checkbox"/> Diarrhea | <input type="checkbox"/> Other: _____ |



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Post-Exposure Prophylaxis

Post-Exposure Prophylaxis (PEP): Individuals who are [not fully vaccinated](#) or who are not expected to mount an adequate immune response to [complete SARS-CoV-2 vaccination](#) (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) **AND**

- have been exposed to an individual infected with SARS-CoV-2 consistent with [close contact criteria per CDC](#) **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)

Vaccination Status (must answer yes to one criteria for eligibility)	Yes	No
Patient <u>not</u> fully vaccinated (<2 weeks from 2 nd dose of 2 nd dose series or <2 weeks from single dose injection)		
Patient <u>not</u> expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (i.e. immunocompromised or taking immunosuppressive medications)		
Exposure (must answer yes to one criteria for eligibility)	Yes	No
Patient has been in close contact (<6 feet distance for >15 minutes) to an infected individual		
Patient high risk of exposure because of infection in the same institutional setting (i.e. nursing homes, prisons)		

I have confirmed that the patient is interested in receiving the monoclonal antibody treatment

Office of the Assistance Secretary of Preparedness and Response (ASPR)

NOTE: The availability of this post-exposure COVID-19 treatment DOES NOT replace vaccination as the most effective way to prevent hospitalizations and deaths from COVID-19. REGEN-COV is not currently authorized for pre-exposure prophylaxis for prevention of COVID-19.