

**To:** Yale New Haven Health Medical Staff

**From:** YNHHS Antimicrobial Stewardship Committee

**Subject:** Clarification of YNHHS criteria for the use of monoclonal antibody therapy for the outpatient treatment of mild to moderate COVID-19 in vaccinated individuals

**Date:** August 30, 2021

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**S:** The use of monoclonal antibody therapy in nonhospitalized patients with mild to moderate COVID-19 who are at high risk for disease progression has been associated with a reduced risk of hospitalization and death. There is a need for clarification on individuals who are vaccinated against COVID-19.

**B:** Monoclonal antibody therapy has been granted emergency use authorization by the FDA for the treatment in nonhospitalized patients with mild to moderate COVID-19 who are at high risk for disease progression has been associated with a reduced risk of hospitalization and death.

The EUA criteria does not address whether or not a patient has been vaccinated against COVID-19.

The NIH guidance suggests that “for people who develop COVID-19 after receiving SARS-CoV-2 vaccination, prior vaccination should not affect treatment decisions, including the use of and timing of treatment with monoclonal antibodies.”

**A:** Clarification on the YNHHS criteria is needed to address individuals who have been vaccinated against COVID-19.

**R:** YNHHS will continue to utilize the emergency use authorization (EUA) criteria for monoclonal antibody therapy for the outpatient treatment of mild to moderate COVID-19 regardless of vaccine status. Details from the patient selection criteria section of the EUA is shown in the appendix.

**Appendix:** Anonymous. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Regen-COV™ (casirivimab and imdevimab), p. 7-8.

**Treatment:**

This section provides essential information on the unapproved product, REGEN-COV (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab) supplied as individual vials to be administered together, for the treatment of adult 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 (1.1)].

**Post-Exposure Prophylaxis:**

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, in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for the post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and 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 Centers for Disease Control and Prevention (CDC)<sup>3</sup> **or**
    - o who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons) [see Limitations of Authorized Use (1.2)].

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  $\geq 65$  years of age)
- Obesity or being overweight (for example, BMI  $> 25$  kg/m<sup>2</sup>, or if age 12-17, have BMI  $\geq 85$ th percentile for their age and gender based on CDC growth charts, [https://www.cdc.gov/growthcharts/clinical\\_charts.htm](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-ncov/need-extra-precautions/people-with-medical-conditions.html>. Healthcare providers should consider the benefit-risk for an individual patient.