



September 14, 2021

Dear Healthcare Provider:

San Bernardino County is receiving allocations of monoclonal antibody therapy, REGEN-COV, (casirivimab and imdevimab), COVID-19 therapeutic medications which have received Emergency Use Authorizations (EUAs) from the U.S. Food and Drug Administration (FDA) in November 2020. Early evidence shows that these treatments show potential to reduce hospitalization for high-risk infected people if given early in infection and to prevent infection in high-risk patients with significant exposure to COVID-19.

The FDA has issued an EUA to permit the emergency use of 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 **mild to moderate coronavirus disease 2019 (COVID-19)** in 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. A new indication is for use in preventing infection (post exposure prophylaxis) in high-risk patients who are exposed.

#### Limitations of Authorized Use:

REGEN-COV (casirivimab and imdevimab) is **NOT** authorized for use in patients:

- 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 co-morbidity.

\*Monoclonal antibodies, such as REGEN-COV, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

#### Post-Exposure Prophylaxis

This EUA is for the use of 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, in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for 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:

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- 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 Center for Disease Control and Prevention (CDC) or,
- 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 the [EUA's Limitations of Authorized Use \(1.2\)](#)].

### **Criteria for Identifying High Risk Individuals**

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

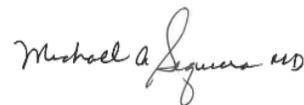
If your facility has patients who are candidates for REGEN-COV treatment, please contact the County SNF Task Force Outreach and Support (SOS) team by calling Heather Morse at (520) 603-6172.

### **References:**

1. [Fact Sheet for Patients, Parents, and Caregivers EUA of REGEN-COV \(casirivimab and imdevimab\)](#)
2. [Fact Sheet for Healthcare Providers EUA of REGEN-COV \(casirivimab and imdevimab\)](#)
3. REGEN-COV Nurse Handout (See e-mail attachment)

Thank you for your continued partnership with the County as we continue to address COVID-19 at your facilities.

Regards,



Michael A. Sequeira, M.D.  
San Bernardino County Department of Public  
Health Officer