

To: CAHAN San Diego Participants

Date: July 22, 2021

From: Public Health Services

Health Advisory Update #37: Coronavirus Disease 2019 (COVID-19) Monoclonal Antibody Therapies

Key Messages

- Combination therapy casirivimab and imdevimab (REGEN-COV™) is recommended for treatment of persons in California aged 12 years and over with mild to moderate COVID-19 and who are at risk for progression for severe disease. **Treatment is expected to reduce hospitalizations and deaths** regardless of the SARS-CoV-2 variant causing COVID-19, including the now dominant delta variant.
- Providers should consider the risk/benefit of monoclonal antibody treatment as soon as possible for symptomatic COVID-19 patients diagnosed by direct SARS-CoV-2 viral testing (includes rapid antigen and PCR tests) regardless of COVID-19 vaccination status (unvaccinated, partially vaccinated, or fully vaccinated).
- Providers may arrange treatment at no cost to the patient regardless of insurance or immigration status by calling 619-685-2500 (patients can self-refer).

Situation

The Centers for Disease Control and Prevention (CDC) recommends monoclonal antibody treatment for mild to moderate COVID-19 who are at high risk for progression to severe disease (hospitalization or death). The diagnosis of COVID-19 can be made by any positive result of direct SARS-CoV-2 viral testing, which includes rapid antigen tests. The specific indications, which include pregnancy, are listed in the accompanying document and linked here. In California, casirivimab and imdevimab (REGEN-COV™) are available and clinically effective against the circulating SARS-CoV-2 variants, including the delta variant. The currently authorized dose to 1,200 mg (600 mg casirivimab and 600 mg imdevimab) can be given by intravenous (IV) infusion or subcutaneously when IV infusion would lead to treatment delay. Treatment should be given as early as possible and includes patients under evaluation in skilled nursing facilities, assisted living facilities, and patients under evaluation in emergency departments.

According to CDC, treatment is <u>clinically effective in persons who have received one or more doses of COVID-19 vaccine</u>. Vaccination should not affect treatment decisions of monoclonal antibodies or timing of such treatments. However, if a person has received monoclonal antibody treatment, initial or subsequent doses of COVID-19 vaccines should be deferred for at least 90 days based on current evidence.

Treatment with monoclonal antibody therapy is underutilized in San Diego County despite being available within several local healthcare systems. Treatment at no cost to the patient regardless of health insurance or immigration status is available at two Monoclonal Antibody Regional Centers (MARCs) in the county and two Family Health Centers of San Diego (FHCSD) sites. Providers may refer patients and patients can self-refer using the information below.

Actions Requested

- 1. Test symptomatic patients for COVID-19.
- 2. Refer COVID-19 patients at high-risk for disease progression for monoclonal antibody treatment as early as possible in their disease, for greatest effectiveness while their symptoms are still mild or moderate. The only monoclonal therapy recommended in California at this time is the combination of casirivimab and imdevimab.
- 3. Note that treatment is available at no cost to the patient regardless of health insurance or immigration status, at two Monoclonal Antibody Regional Centers (MARCs) and two Family Health Centers of San Diego (FHCSD) sites.
 - To refer patients
 - Call 619-685-2500 (patients can self-refer);
 - Email questions to COVIDtreatment@sdcounty.ca.gov;

Resources

Fact sheet for Healthcare Providers: Casirivimab and Imdevimab

Fact sheet for Patients, Parents, and Caregivers: Casirivimab and Imdevimab (Spanish Version)

NIH: Non hospitalized Adults: Therapeutic Management | COVID-19 Treatment Guidelines (nih.gov); Anti-SARS-CoV-2

Monoclonal Antibodies | COVID-19 Treatment Guidelines (nih.gov)

IDSA: Monoclonal Antibodies (idsociety.org)

ACEP: ACEP // ACEP Statement on Monoclonal Antibody Infusion

AAFP: Monoclonal Antibody Approved (aafp.org)

Thank you for your participation.

CAHAN San Diego

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INDICATIONS FOR MONOCLONAL ANTIBODY THERAPY

REGEN-COV (casirivimab and imdevimab) is recommended in California, 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 SARS-CoV-2 viral testing (includes rapid antigen and PCR tests) who are at high risk for progression to severe COVID-19, regardless of COVID-19 vaccination status (unvaccinated, partially vaccinated, or fully vaccinated). Refer COVID-19 patients at high-risk for disease progression for monoclonal antibody treatment as early as possible in their disease, for greatest effectiveness while their symptoms are still mild.

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 ≥85th 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 (e.g., race, ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the Emergency Use Authorization (EUA) is not limited to the medical conditions or factors listed above. Additional information on medical conditions and risk factors may be found at the Centers for Disease Control and Prevention website Certain Medical Conditions and Risk for Severe COVID-19 Illness.

Treatment with monoclonal antibody is available at no cost for persons who are medically eligible by calling the MARC line at 619-685-2500 (patients may self-refer). Email questions to coviDtreatment@sdcounty.ca.gov.

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