



To: CAHAN San Diego Participants

Date: May 20, 2021

From: Medical Care Services

Health Advisory Update #34 Coronavirus Disease 2019 (COVID-19) Update: Expansion of Monoclonal Antibody Indications

Key Messages

Emergency Use Authorizations (EUAs) of combination monoclonal antibody therapies with bamlanivimab/etesevimab and casirivimab with imdevimab (REGEN-COV™) in the treatment of mild to moderate COVID-19 have been greatly expanded.

Providers should consider the risk/benefit of monoclonal antibody treatment as soon as possible for symptomatic COVID-19 patients. Those eligible for treatment include **newly specified groups listed below in this advisory, as well as other medical conditions or factors. Race and ethnicity may also place individual patients at high risk for progression to severe COVID-19.** Hispanic/Latino, Black and Native Hawaiian/Pacific Islander residents have the highest hospitalization and death rates in San Diego County.

Monoclonal antibodies are underutilized, and capacity to provide treatment is available at no cost to the patient regardless of health insurance or immigration status, at two Monoclonal Antibody Regional Centers (MARC) and two Family Health Centers of San Diego (FHCS) sites.

Situation

The U.S. Food and Drug Administration (FDA) recently expanded the Emergency Use Authorizations (EUA) of the combination monoclonal antibody therapies in the treatment of mild to moderate COVID-19 in persons at high risk for progressing to severe COVID-19. FDA has updated the [Fact Sheet for Health Care Providers EUA of Bamlanivimab and Etesevimab](#) and the [Fact Sheet for Health Care Providers EUA of REGEN-COV™ \(Casirivimab with Imdevimab\)](#).

Persons eligible for combination treatment are those with a positive direct SARS CoV-2 viral test who are at least 12 years of age (and weighing at least 40 kg), have mild to moderate symptoms for 10 days or less, and are at high-risk for disease progression. The following are examples of risk groups and conditions placing individuals at high risk for progression (newly added criteria **bolded**):

- Older age (for example age ≥65 years of age);
- 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](#));
- **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]); and
- **Other medical conditions or factors including race and ethnicity that may also place individual patients at high risk for progression to severe COVID-19.**

Utilization of combination monoclonal antibody therapies under the EUA is **not limited** to the medical conditions or factors listed above, and additional information may be found at the Centers for Disease Control and Prevention website [Certain Medical Conditions and Risk for Severe COVID-19 Illness](#). Healthcare providers should consider the benefit-risk of these therapies for individual patients. Medical conditions for which monoclonal antibody treatment is not authorized are listed in the FDA fact sheets for [Bamlanivimab and Etesevimab](#) and [Casirivimab with Imdevimab](#).

Treatment with combination 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 \(MARC\)s](#) in the County and two [Family Health Centers of San Diego \(FHCS\)D](#) sites. Providers may refer patients and patients can self-refer using the information below. Locations providing therapy may change; providers should confirm locations on the respective websites.

Actions Requested

1. Test symptomatic patients for COVID-19.
2. Refer patients at high-risk for disease progression for treatment **as early as possible in their disease, [for greatest effectiveness](#) while their symptoms are still mild.**
3. To refer patients to the [Monoclonal Antibody Regional Centers \(MARC\)s](#) (open 7 days a week):
 - Call 619-685-2500 (patients can self-refer),
 - Email [referral form](#) or questions to COVIDtreatment@sdcounty.ca.gov, and
 - Fax [referral form](#) to Palomar Medical Center at 760-739-2851 or San Ysidro Health at 619-785-3293.
4. To refer patients to [Family Health Centers of San Diego \(FHCS\)D](#) sites:
 - Call 619-906-5420 (patients can self-refer),
 - Email: covidcare@fhcsd.org, and
 - Schedule on-line using [MyHealthRecord](#).

Resources

Fact sheets for Healthcare Providers: [Bamlanivimab plus Etesevimab](#) and [Casirivimab with Imdevimab](#)

Fact sheets for Patients, Parents, and Caregivers: [Bamlanivimab plus Etesevimab](#) and [Casirivimab with Imdevimab](#)

Thank you for your participation.

CAHAN San Diego

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