



**To: CAHAN San Diego Participants**

**Date: June 4, 2021**

**From: Public Health Services**

**Health Advisory Update #36: Coronavirus Disease 2019 (COVID-19) Monoclonal Antibody Therapies.**

#### **Key Messages**

- Bamlanivimab plus Etesevimab therapy is no longer recommended due to variant resistance in California. Providers can still use casirivimab plus imdevimab.
- The Food and Drug Administration (FDA) has updated the Emergency Use Authorization (EUA) for REGEN-COV™, lowering the dose to 1,200 mg (600 mg casirivimab and 600 mg imdevimab), and adding the subcutaneous route of administration.
- FDA has issued an EUA for sotrovimab, a new monoclonal antibody therapy with the same indications as casirivimab plus imdevimab. It is anticipated that sotrovimab will be available soon in California.

#### **Situation**

The Centers for Disease Control and Prevention (CDC) has identified that the combined frequency of the P.1 (Brazil) and the B.1.351 (South Africa) variants now exceed 10% in California. Results from in vitro assays of monoclonal antibodies suggest that both the P.1 and B.1.351 variants have significantly reduced susceptibility to the combination therapy bamlanivimab plus etesevimab. Distribution of bamlanivimab and etesevimab to California has ceased and the Food and Drug Administration (FDA) recommends that until further notice healthcare providers in California use casirivimab plus imdevimab (i.e., REGEN-COV™) for patients at high risk for COVID-19 disease progression.

In addition, FDA has updated the Emergency Use Authorization (EUA) for REGEN-COV™, halving the originally authorized dose to 1,200 mg (600 mg casirivimab and 600 mg imdevimab). The change is supported by pivotal Phase 3 data showing the 1,200 mg dose reduced risk of hospitalization or death by 70%. The higher dose had a similar efficacy of a 71% reduction compared to placebo. Subcutaneous administration has also been authorized when intravenous (IV) infusion is not feasible and would lead to treatment delay.

The FDA has issued an [EUA](#) for sotrovimab, a monoclonal antibody therapy for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients. The dose of sotrovimab is 500 mg administered by IV infusion over 30 minutes. Sotrovimab reduced progression of COVID-19 at day 29 by 85% compared to placebo. The indications for this product are the same as those for casirivimab plus imdevimab.

#### **Monoclonal Antibody Regional Centers**

**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 \(MARC\)](#)s in the County and two [Family Health](#)

[Centers of San Diego \(FHCSO\)](#) 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 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** but the only recommended treatment available in California at this time is casirivimab plus imdevimab.
3. Take note of the new authorized dosing and option of subcutaneous administration for casirivimab plus imdevimab.
4. Note that 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 (FHCSO) sites.
  - To refer patients to the [Monoclonal Antibody Regional Centers \(MARC\)](#) (open 7 days a week):
    - Call 619-685-2500 (patients can self-refer);
    - Email [referral form](mailto:referral_form) or questions to [COVIDtreatment@sdcounty.ca.gov](mailto:COVIDtreatment@sdcounty.ca.gov);
    - Fax [referral form](#) to Palomar Health/Pomerado Pavilion at 760-739-2851 or San Ysidro Health at 619-785-3293.
  - To refer patients to [Family Health Centers of San Diego \(FHCSO\)](#) sites:
    - Call 619-906-5420 (patients can self-refer);
    - Email: [covidcare@fhcsd.org](mailto:covidcare@fhcsd.org);
    - Schedule on-line using [MyHealthRecord](#).
5. Be aware that a new monoclonal therapy, sotrovimab, has received an EUA and may soon become available in California.

## Resources

CDPH CAHAN: [Bamlanivimab plus Etesevimab No Longer Recommended for Use in California for COVID-19](#)

HHS: [Cessation in distribution of bamlanivimab and etesevimab to specific states](#)

Fact sheet for Healthcare Providers: [Casirivimab plus Imdevimab](#)

Fact sheet for Healthcare Providers: [Sotrovimab](#)

Fact sheet for Patients, Parents, and Caregivers: [Casirivimab plus Imdevimab](#)

Fact sheet for Patients, Parents, and Caregivers: [Sotrovimab](#)

Thank you for your participation.

## CAHAN San Diego

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**Health Alert:**

**Bamlanivimab plus Etesevimab No Longer Recommended for Use in California for COVID-19**

**On May 26, 2021, given the sustained increase in the P.1 and B.1.351 variants, the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) stopped the distribution of bamlanivimab plus etesevimab to California.** The Centers for Disease Control and Prevention (CDC) has identified that the combined frequency of the P.1 variant and the B.1.351 variant now exceeds 10% in California. Results from in vitro assays that are used to assess the susceptibility of viral variants to particular monoclonal antibodies suggest that bamlanivimab and etesevimab administered together are not active against either the P.1 or B.1.351 variants.

**The FDA recommends that health care providers in California instead use casirivimab plus imdevimab (i.e., REGEN-COV) therapy until further notice.** Casirivimab plus imdevimab is an alternative monoclonal antibody therapy that is currently authorized for the same use as bamlanivimab plus etesevimab. Based on similar in vitro assay data currently available, casirivimab plus imdevimab is likely to retain activity against the P.1 and B.1.351 variants. **All treatment sites can continue ordering casirivimab plus imdevimab from the authorized distributor using the [direct ordering](#) process.**

Please see the [HHS/ASPR notice](#) regarding this update for more information.

