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Alameda County Health Advisory
Monoclonal Antibody (MAB) Therapy Outpatient Infusion Resources in Alameda County

March 8, 2021 (Revised November 3, 2021)

Revisions in Red

The purpose of this Health Advisory is to inform clinicians in Alameda County about the availability of **outpatient monoclonal antibody (MAB) therapy for high-risk patients** with mild to moderate SARS-CoV-2 infections who are not yet hospitalized due to COVID. In addition, REGEN-COV and bamlanivimab + etesevimab are now authorized for use as post-exposure prophylaxis (PEP) for patients who are at high risk for progression to severe COVID-19. MAB therapy is recommended in the *NIH COVID-19 Treatment Guidelines*.

Casirivimab + imdevimab (i.e. REGEN-COV), bamlanivimab + etesevimab and sotrovimab are investigational MAB products available under Emergency Use Authorization (EUA) from the FDA. **Because the combination of bamlanivimab + etesevimab retains activity against the Delta variant in California, their use and distribution have been resumed**. All these MAB products have been structured to bind to and neutralize SARS-CoV-2 and prevent progression to severe illness. There are data suggesting that early outpatient treatment with MAB therapy may shorten the duration of symptoms; decrease the viral load; and prevent some ED visits, hospitalizations, and deaths in high-risk individuals. REGEN-COV is approved for subcutaneous injection as an alternative when intravenous (IV) infusion is not feasible and would lead to delay in treatment. The use of bamlanivimab + etesevimab or sotrovimab is restricted to IV infusion only. ~~The use of bamlanivimab + etesevimab is not currently recommended for patients infected in Hawaii.~~

Actions Requested of Clinicians

ACPHD recommends that clinicians with patients who meet the inclusion criteria for the use of outpatient MABtherapy, as described below, contact the following entities or other participating medical systems for information on treatment availability. *Treatment should be coordinated in advance of sending a patient for therapy.*

Outpatients:

- Total Infusion - Eastmont Town Center, Oakland: (510) 878-9528

  Click here to make a referral to Total Infusion

LTCF Residents:

- Specialty Pharmacy associated with the LTCF

If timely appointments in Alameda County are not available for your patients, you can contact the hospitals below:

- **UCSF:** UCSF Monoclonal Antibody Use Process *(complete/fax referral document, including for 12 to 17 year-olds).* Questions? Contact COVIDOutpatientTreatment@ucsf.edu
- **Stanford Medical Center, Palo Alto:** Contact DL-SHC-PHARMACY-COVID@stanfordhealthcare.org or (650) 391-8503.
  - Stanford's website has information for patients and health care providers on MAB.

Inclusion criteria for the use of outpatient monoclonal antibody therapy are as follows:

1. **Treatment:**
   - **Positive SARS-CoV-2 PCR or antigen test**
   - **Mild to moderate COVID-19 symptoms for 10 days or less**. Ideally, antibody therapy would begin within 3days of a positive test.
   - Weight is **≥40 kg.**
   - **High risk for progressing to severe COVID-19 and/or hospitalization** due to any of the following:
     - Obesity or being overweight (for example, body mass index (BMI) ≥25, or if age 12-17, have BMI ≥85th percentile for age and gender based on CDC growth charts
     - Older age (≥65 years of age)
     - Pregnancy
     - Diabetes, chronic kidney disease, immunosuppressive disease, or current receipt of immunosuppressive treatment
     - Cardiovascular disease (including congenital heart disease) or hypertension
     - Chronic lung diseases (e.g. chronic obstructive pulmonary disease, moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
     - Sickle cell disease
     - Neurodevelopmental disorders (e.g. cerebral palsy) or other conditions that confer medical complexity (e.g. genetic or metabolic syndromes and severe congenital anomalies)
     - Medically-related technological dependence (e.g. tracheostomy, gastrostomy, or positive pressure ventilation unrelated to COVID-19)
   - **Other medical conditions or factors (e.g. race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19. Authorization under the EUAs is not limited to the list above.**

2. **Post-exposure prophylaxis (PEP) (REGEN-COV or bamlanivimab + etesevimab):**
   - Individuals 12 years of age and older (≥40 kg) who have had close contact with a positive case **OR** who are at high risk of exposure to an individual with COVID-19 because of other positive cases in the same institutional setting (e.g., nursing homes, prisons) **AND** who are:
     1. Not fully vaccinated or not expected to mount an adequate immune response to full vaccination (e.g., individuals with immunocompromising conditions including those taking immunosuppressive medications) **AND**
     2. At high risk for progressing to severe COVID-19 (see criteria listed above).

These monoclonal antibody products are NOT authorized for use in patients who are hospitalized due to COVID-19 or who require supplemental O2 therapy or an increase flow rate from baseline home O2 therapy. They may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or *mechanical ventilation.*

NOTES

- See REGEN-COV for updated dosing and preparation instructions. Note that the *repeat* dosage for PEP in patients with an ongoing exposure is different than the initial *standard* dosage.
- **Follow AmerisourceBergen's instructions related to packaging and temporary dosing changes.** There are 2 packaging configurations. **One of the dosing packages may bear the ROCHE label** instead of the REGEN-COV label.
- See updated bamlanivimab/etesevimab EUA.
- Circulating SARS-CoV-2 viral variants may be associated with resistance to MAB therapy.
- Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people who received monoclonal antibodies. **Vaccination should be deferred for at least 90 days.**
- Prior receipt of a COVID-19 vaccine should NOT affect COVID-19 treatment decisions, including use of monoclonal antibodies.
- These MAB products are NOT authorized for **pre**-exposure prophylaxis for prevention of COVID-19.
- These MAB products may only be administered in settings where health care providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

For general/eligibility questions: Contact the Combat COVID Monoclonal Antibodies Call Center at 1-877-332-6585

For questions regarding the distribution of monoclonal antibody supplies within ALCO, please contact CynthiaFrankel, RN, Alameda County MAB Distribution Lead at cynthia.frankel@acgov.org

For clinical questions about treatment with monoclonal antibodies, please contact Arnie Spanjers, MD, Alameda County Public Health Department at arnie.spanjers@acgov.org