Health Advisory
January 4, 2021
Monoclonal Antibody Treatments for COVID-19

The Fresno County Department of Public Health (FCDPH) is recommending monoclonal antibodies (Bamlanivimab and Regeneron) as COVID-19 treatment options available to healthcare providers.

Fresno County emergency rooms and hospitals continue to be filled to capacity. Monoclonal antibodies are an important tool in keeping patients from deteriorating and to assist the health care system from becoming overwhelmed. Preliminary data suggests a 2/3 to 3/4 reduction in emergency room visits and hospitalizations among high-risk COVID-19 positive patients who received monoclonal antibodies.

Who is Eligible to Receive Monoclonal Antibodies?
Monoclonal antibodies have Federal Drug Administration (FDA) emergency use approval for the treatment of mild to moderate COVID-19 positive patients within the first 10 days of diagnosis who are at high risk for progressing to severe COVID-19 and/or hospitalization. High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have
  - Cardiovascular disease, OR
  - Hypertension, OR
  - Chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 – 17 years of age AND have
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- BMI ≥85th percentile for their age and gender based on Centers for Disease Control and Prevention (CDC) growth charts: https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
- Sickle cell disease, OR
- Congenital or acquired heart disease, OR
- Neurodevelopmental disorders, for example, cerebral palsy, OR
- A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
- Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

Monoclonal antibodies are 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 comorbidity. There are no contraindications to providing the monoclonal antibodies.

What information can I give my patients about monoclonal antibodies?
As a healthcare provider, you must communicate to your patient or parent/caregiver, as age appropriate, information consistent with the “Fact Sheet for Patients, Parents and Caregivers” (and provide a copy of the Fact Sheet- links to both monoclonal antibodies are provided below) prior to the patient receiving monoclonal antibodies, including:
- The FDA has authorized the emergency use of monoclonal antibodies for the treatment of mild to moderate COVID-19 in adult patients with positive results of COVID-19 testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization
- The patient or parent/caregiver has the option to accept or refuse the monoclonal antibody treatment
- The significant known and potential risks and benefits of monoclonal antibodies, and the extent to which such potential risks and benefits are unknown
- Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.
- Patients treated with monoclonal antibodies should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to CDC guidelines.

Fact Sheet Links:

Per the National Institutes of Health (NIH):
"In the earliest stages of infection, before the host has mounted an effective immune response, anti-SARS-CoV-2 antibody-based therapies may have their greatest likelihood of having an effect. In this regard, although there
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are insufficient data from clinical trials to recommend either for or against the use of any specific therapy in this setting, preliminary data suggests that outpatients may benefit from receiving anti-SARS-CoV-2 monoclonal antibodies early in the course of infection. The anti-SARS-CoV-2 monoclonal antibodies bamlanivimab and casirivimab plus imdevimab are available through Emergency Use Authorizations for outpatients who are at high risk for disease progression."

In a post hoc analysis of participants at higher risk for hospitalization (using the definition of high risk in the EUA, and thus approximating the population that would be recommended for treatment with casirivimab plus imdevimab per the EUA), four of 151 participants (3%) in the pooled casirivimab plus imdevimab arms versus seven of 78 participants (9%) in the placebo group were hospitalized or had emergency department visits.

In a separate analysis of the BLAZE-1 study reported in the EUA of participants at high risk for hospitalization (using an expanded definition that approximates criteria for those who should be treated with bamlanivimab through the EUA), four of 136 (2.9%) participants in the combined bamlanivimab arms versus seven of 69 (10.1%) participants in the placebo group were hospitalized or had emergency department visits.

https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/

Where can my patients receive monoclonal antibodies?
ALL PATIENTS NEED TO HAVE PRE-APPROVAL, AND THE INFUSIONS ARE NOT AVAILABLE ON A "WALK-IN" BASIS. Please contact the individuals or sites beforehand to coordinate inclusion criteria, and an appointment date and time.

Local hospitals have received allotments of monoclonal antibodies. Several community-based providers are also offering monoclonal antibodies. See contact information below:

- St. Agnes - Paul LeBlanc paul.leblanc@samc.com
- Kaiser - Tim J. Sayles Tim.J.Sayles@kp.org
- Adventist Reedley/Selma – Ed Abukhazneh AbukhaAF@ah.org (Contact the Adventist Health emergency room in Reedley and Selma to arrange for an infusion)
- Bautista Medical Group (c/o Office Manager Araceli) - (559) 252- 7301 Fax (559) 252-1419 jgb2106@yahoo.com
- Coalinga Regional Medical Center - Matt Salas msalas@crmcmed.org (559) 821-6034 ext. 105

These infusion sites may request that you verify that the patient is eligible for monoclonal antibody infusion, including that COVID-19 positive in last 10 days, meets high risk criteria, currently with no, mild, or moderate symptoms (no O2 requirement) and that the patient has been given information about monoclonal infusions (see above section with links to patient information).
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Can I give monoclonal antibodies in my office or health care setting?
Yes, you can. There are two monoclonal antibody products with FDA emergency use authorizations, bamlanivimab, and casirivimab plus imdevimab (see below links). Monoclonal antibodies are administered over one hour with an IV infusion and must be monitored for one hour after for any reactions- specific dosing. The mechanics of storing, mixing, dosing, and administering monoclonal antibodies is described in the below information for healthcare providers.

Per the NIH, “There are currently no comparative data to determine whether there are differences in clinical efficacy or safety between casirivimab plus imdevimab and bamlanivimab.”

Monoclonal Antibody Product Links:

At this point, the monoclonal antibodies are provided free of charge through the Centers for Medicare and Medicaid Services (CMS) and the State of California. The CMS reimburses healthcare providers for the infusion.

Three local compounding pharmacies (Model Drug in Kingsburg, Pharmerica, and AlixaRx) can provide your office with the monoclonal antibodies. Community Regional Medical Centers is prepared to redirect monoclonal antibody doses to sites that are prepared to offer the infusions. Their contact information is included below.

- Model Drug Inc. - Natalie Kennedy natalie@modeldrug.com (559) 897-1926
- Pharmerica - Diane Lima Diane.Lima@pharmerica.com (559) 499-9079
- AlixaRx - Darlene Ervin Darlene.ervin@alixarx.com (559) 277-4100
- Community Medical Centers - Stephen Rettig SReyttig@communitymedical.org
- Community Medical Centers - Amy Royston ARoyston@communitymedical.org

If you have any questions or challenges with accessing or administering monoclonal antibodies, please contact FCDPH Public Health Physicians. Contact information is included below:

- Dr. John Zweifler j Zweifler@fresnocountyca.gov
- Dr. Robin Linscheid rlinscheidjanzen@fresnocountyca.gov

Thank you for making this life-saving treatment available to your COVID-19 positive patients.