Monoclonal Antibody (MAB) Treatment for COVID-19

COVID-19 is a viral respiratory infection caused by the SARS-CoV-2 coronavirus which may cause symptoms that range from mild to severe illness and possibly death. The FDA has authorized the emergency use of monoclonal antibody products for the treatment of mild to moderate COVID-19 disease and post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19.

For the most complete and up-to-date prescribing information regarding monoclonal antibody treatments, please refer to the most current monoclonal antibody treatment fact sheets and FDA and CDPH guidelines.

Requests for MAB treatment should be submitted through the authorization portal and will be expedited by Regal, Lakeside, ADOC and Greater Covina Pharmarcy team.

Who can get the Monoclonal Antibody (MAB) Treatment?

a) **High risk patients defined by meeting at least one of the following criteria:**

- Seniors (age 65 years and older)
- 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 currently receiving 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 (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extraprecautions/ people-with-medicalconditions. html. Healthcare providers should consider the benefit-risk for an individual patient.

b) **Exclusion criteria:**

- Hospitalized due to COVID-19
- Require oxygen therapy due to COVID-19
- 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 morbidity
- Monoclonal antibodies, such as REGENCOV, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation
- Post-exposure prophylaxis with REGENCOV (casirivimab and imdevimab) is not a substitute for vaccination against COVID-19
- REGEN-COV (casirivimab and imdevimab) is not authorized for pre-exposure prophylaxis for prevention of COVID-19

c) **Circulating SARS-CoV-2 viral variants** may be associated with resistance to monoclonal antibodies. Healthcare providers should review the Antiviral Resistance information in Section 15 of this Fact Sheet for details regarding specific variants and resistance, and refer to http:// publichealth.lacounty.gov/eprp/lahan/alerts/CAHANBamlanivimabandSARSCoV2Variants. pdf as well as information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

Regal/Lakeside is available to answer all of your questions and offer support and education to providers.

Where can patients get the Monoclonal Antibody (MAB) Treatment?

- Home and Ambulatory Infusion Centers (POS =12) Contracted with: OSO Specialty Infusion Services
  - Referral/Intake Contact: Phone (800) 310-6611; Fax (866) 800-6313
  - Place of Service: POS =12
- OSO Ambulatory Infusion Center Locations:

Burbank
- (818) 557-0308
- 2811 N. Lima St.
  Burbank, CA 91504

Irvine
- (949) 660-7126
- 17175 Gillette Ave.
  Irvine, CA 92614

Lancaster
- (818) 557-0308
- 44215 15th St. West
  Ste. 209
  Lancaster, CA 93534

Long Beach
- (800) 310-6611
- 911 E. San Antonio Dr.
  Ste. 3
  Long Beach, CA 90807

Los Angeles
- (800) 310-6611
- 1950 Sawtelle Blvd., Ste. 138
  Los Angeles, CA 90025

Pasadena
- (800) 310-6611
- 301 S. Fair Oaks Ave., Ste. 401
  Pasadena, CA 91105

Redlands
- (909) 793-3868
- 76 Alabama St.
  Redlands, CA 92373

What are the administration codes?

- Outpatient/Home Infusion Center:
  - **M0243:** REGEN-COV (casirivimab and imdevimab)
  - Administration: **99601**

This EUA is also for the use of unapproved products, REGEN-COV (casirivimab with imdevimab) coformulated product and REGEN-COV (casirivimab and imdevimab) supplied as individual vials to be administered together, in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are: not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) and have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Center for Disease Control and Prevention (CDC) or who are at high risk of exposure to an individual infected with SARS-CoV2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons) [see Limitations of Authorized Use (1.2).

Additional Information:

- Refer to Antiviral Resistance information on EUA Factsheets of these monoclonal antibody therapies for details regarding specific variants and resistance and refer to information provided by state and local health authorities regarding reports of viral variants of importance in your region. http://publichealth.lacounty.gov/eprp/lahan/alerts/CAHANBamlanivimabandSARSCoV2Variants.pdf
- Provide and communicate information consistent with "Fact Sheets for Patients, Parents, and Caregivers."
- Inform that these are unapproved treatments that are authorized for use under Emergency Use Authorization.
- Report all medication errors/serious adverse events potentially related to monoclonal antibody therapies within 7 calendar days from the onset of the event.
- Report adverse events to FDA MedWatch.
- Report therapeutics information and utilization data through HHS Protect, Teletracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services.

References:

- CMS
- https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion
- FDA
- https://www.fda.gov/media/145611/download
- https://www.fda.gov/media/145612/download
- CDPH
- http://publichealth.lacounty.gov/eprp/lahan/alerts/CAHANBamlanivimabandSARSCoV2Variants.pdf
- https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Monoclonal-Antibody-Treatment-Information-for-Providers-and-Facilities.aspx#
- NIH
- https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2- monoclonal-antibodies/