Anti-SARS-COV-2 Monoclonal Antibodies

How they work

- Synthetic antibodies that bind to the spike protein of SARS-COV-2, blocking the virus' ability to enter human cells
- Reduces the risk of severe illness and hospitalization in high-risk **outpatients** with mild to moderate COVID-19
- Can be used to decrease the chances of developing COVID-19 **after an infectious exposure** (as a post-exposure prophylaxis) in certain at-risk individuals

Anti-SARS-COV-2 Monoclonal Antibodies as a Treatment

- For the treatment of **mild to moderate** COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization
- High risk categories include: older age, being overweight/obese, pregnancy, chronic kidney disease, diabetes, immunosuppression, cardiovascular disease or hypertension, chronic lung diseases, sickle cell disease, neurodevelopmental disorders, having a medical-related technological dependence, or other medical conditions or that may also place individual patients at high risk
- Ideally given within 10 days of symptom onset
- Should not be used for patients that are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19

Anti-SARS-COV-2 Monoclonal Antibodies as a Post-Exposure Prophylaxis

- Can be considered in individuals **who are not fully vaccinated** or individuals who are **not expected to mount an adequate immune response** to SARS-CoV-2
- Post-exposure prophylaxis can be given to these individuals if:
  - They have been exposed to an individual infected with SARS-CoV-2 consistent with the Centers for Disease Control and Prevention (CDC) close contact criteria (less than 6 feet away from infected person for a cumulative total of 15 minutes or more over a 24-hour period); OR
  - They are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting.
- For individuals who have recurrent exposures for a month or more, anti-SARS-CoV-2 monoclonal antibodies can be subsequently dosed every 4 weeks for the duration of the ongoing exposure
- Use of these products as post-exposure prophylaxis is not a replacement for vaccination. Additionally, the drug should not be used as a pre-exposure prophylaxis.

Available Anti-SARS-COV-2 Monoclonal Antibody Products

Product	Indications	Coverage of Variants Circulating in California	Administration	Acquiring Product	Link to Emergency Use Authorization (EUA)
Casirivimab/Imdevimab (REGEN-COV)	• Treatment of mild to moderate outpatients at risk of disease progression • Post-exposure prophylaxis in high risk individuals	Yes	Intravenous; subcutaneous	Federal government allocation of products to states based on previous week indicators; state-coordinated distribution system to facilities through local MHOAC*	https://www.fda.gov/media/145611/download
Bamlanivimab/ Etesevimab	• Treatment of mild to moderate outpatients at risk of disease progression • Post-exposure prophylaxis in high risk individuals	Yes	Intravenous	Federal government allocation of products to states based on previous week indicators; state-coordinated distribution system to facilities through local MHOAC*	https://www.fda.gov/media/145802/download
Sotrovimab	• Treatment of mild to moderate outpatients at risk of disease progression	Yes	Intravenous	Federal government allocation of products to states based on previous week indicators; state-coordinated distribution system to facilities through local MHOAC*	https://www.fda.gov/media/149534/download

*MHOAC contact information: https://emsa.ca.gov/wp-content/uploads/sites/71/2021/09/MHOAC-Contact-List-9.2.2021-Public.pdf

Reporting Utilization

- All healthcare facilities are required to report utilization of anti-SARS-COV-2 monoclonal antibody products.
- Utilization does inform distribution, and failure to report use will result in a decrease in California's allocation from HHS.

Reporting of Anti-SARS-COV-2 Utilization	
Facility Type	**Reporting Mechanism**
Hospital/Hospital Pharmacy	Report mAb utilization and stock on hand via HHS Protect
Long term care facilities/skilled nursing facilities	Report via National Healthcare Safety Network (NHSN)
Non-hospital facilities (i.e. urgent care clinics, dialysis clinics, pharmacies)	Report via HHS TeleTracking COVID-19 Portal