California Department of Public Health
Center for Health Care Quality
AFC Skilled Nursing Facilities Infection Prevention Call
November 3 & 4, 2021

Recordings, notes and slides for the Wednesday Webinars and Thursday calls can be accessed at the Health Services Advisory Group (HSAG) registration website:
https://www.hsag.com/en/covid-19/long-term-care-facilities/cdph-ip-webinars-past/

CDPH Weekly Call-in Information:
Tuesday 8:00am All Facilities Calls: 844.721.7239; Access code: 7993227
Wednesday 3:00pm SNF Infection Prevention Webinars: Register at: https://www.hsag.com/cdph-ip-webinars
Thursday 12:00pm SNF Infection Prevention Calls: 877.226.8163; Access code: 513711

The Wednesday Webinar & Thursday Call covered the following agenda items:

- CMS Newsroom, November 4, 2021: Biden-Harris Administration Issues Emergency Regulation Requiring COVID-19 Vaccination for Health Care Workers
  https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care
  - To view the interim final rule with comment period, visit: https://www.federalregister.gov/public-inspection/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination
  - To view a list of frequently asked questions, visit: www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.docx

- Immunization Branch Updates
  - PPT: https://www.hsag.com/globalassets/covid-19/hsag-vaccine-slides-110321-508.pdf
  - CDC Recommends Pediatric COVID-19 Vaccine for Children 5 to 11 Years: https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html
  - FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age: https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age
  - CDPH COVID-19 Vaccine Product Guide https://eziz.org/assets/docs/COVID19/IMM-1399.pdf
  - CDPH Long-Term Care Facility COVID-19 Vaccine Toolkit https://eziz.org/assets/docs/COVID19/LTCF_Toolkit_10.01.21.pdf
  - CDC Interim Clinical Considerations for Use of COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

- Monoclonal Antibody Updates:
  - PPT: https://www.hsag.com/globalassets/covid-19/monoclonal-antibodies-508.pdf
  - See presentation notes on pages 7-9
  - Combat COVID resources created by the U.S. Department of Health and Human Services (HHS) has the latest resources on COVID-19 news, vaccines, treatments, and research, including guidance documents to help healthcare facilities plan for the use of monoclonal antibody treatments https://combatcovid.hhs.gov/hcp/resources

- Testing Task Force Updates
  - PPT: https://www.hsag.com/globalassets/covid-19/snfnov3-ef-508.pdf
  - 12/10/2020: Lab Advisory: CMS Guidance for the Use of Expired SARS-CoV-2 Tests: https://www.cdc.gov/csels/dls/locs/2020/cms_guidance_for_the_use_of_expired_sars-cov-2_tests.html

- Full Speed Ahead! COVID-19 Recognition Program https://www.hsag.com/en/covid-19/vaccine-resources/#Full_Speed_Ahead_COVID_19_Vaccination_Recognition_Program
  - PPT: https://www.hsag.com/globalassets/covid-19/cdph-november-3-508.pdf (slides 6-8)
  - 86% of California nursing homes achieved >75% staff vaccination rate for four consecutive weeks in quarter three.
  - 45% of California nursing homes achieved >90% resident vaccination rate for four consecutive weeks in quarter four.
  - Certificates of achievement will be emailed to nursing homes that achieved these rates.
  - CMS COVID-19 nursing home vaccine data is public at: https://data.cms.gov/covid-19/covid-19-nursing-home-data

- Clear Pol: https://beta.clearpol.com/
  - Useful website for providers to search for and compare current and past federal and state guidance, including AFLs, QSOs, Title 22, F-tags, PINs, etc.
  - PPT: https://www.hsag.com/globalassets/covid-19/cdph-november-3-508.pdf (slides 9-11)

Important Links to State and Federal Guidance	
Important Links and FAQs to State Guidance	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx
July 26, 2021 State Public Health Officer Order: Health Care Worker Protections in High-Risk Settings	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Order-of-the-State-Public-Health-Officer-Unvaccinated-Workers-In-High-Risk-Settings.aspx
August 5, 2021 State Public Health Officer Order: Health Care Worker Vaccine Requirement	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Order-of-the-State-Public-Health-Officer-Health-Care-Worker-Vaccine-Requirement.aspx
August 5, 2021 State Public Health Officer Order: Requirements for Visitors in Acute Health Care and Long-Term Care Settings	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Order-of-the-State-Public-Health-Officer-Requirements-for-Visitors-in-Acute-Health-Care-and-Long-Term-Care-Settings.aspx
CDPH AFL 21-28: Testing, Vaccination Verification and PPE for HCP at SNFs	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-28.aspx
CDPH AFL 20-22.9: Guidance for Limiting the Transmission of COVID-19 in SNFs	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-22.aspx
CDPH AFL 20-53.5: Mitigation Plan Recommendations for Testing	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-53.aspx
CDPH AFL 21-08.4: Guidance on Quarantine for HCP Exposed to COVID-19	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-08.aspx
CDPH AFL 21-34: COVID-19 Vaccine Requirement for HCP	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-34.aspx
CMS QSO-20-38-NH: Revision to Long-Term Care (LTC) Facility Testing Requirements	https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf

COVID-19 Vaccine Questions & Answers

Q-1: A potential new hire received their first dose of the mRNA vaccine in January but never got a second dose. If they receive another dose now, will they be fully vaccinated, or should they restart the series?
A: CDC guidance does not recommend restarting the series. The ideal window to get the second dose is six weeks, but if that was not possible, the individual should get the second dose as soon as possible, and will be considered fully vaccinated 2 weeks after receiving that dose.

Q-2: On Thanksgiving Day, are fully vaccinated visitors allowed to dine with residents they are visiting in the communal dining room, if other residents whom they are not visiting are 6-feet apart?
A: Yes, fully vaccinated visitors visiting fully vaccinated residents can eat and dine together in the communal dining room without physical distancing. They do not need to wear a mask while they are actively eating and drinking together, as long as they keep 6-feet distancing from other residents and visitors that they are not visiting. See visitation and communal dining guidance in CDPH AFL 20-22.9 (https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-22.aspx). The guidance indicates that "Facilities shall also accommodate visitation in large communal indoor spaces where 6-ft distancing is possible between visitor-resident groups. Facilities may need to rearrange these spaces or add barriers to separate the space to accommodate the need for visitation of multiple residents. During indoor large communal space visits between fully vaccinated residents and fully vaccinated visitors, both the resident and visitor must always wear a well-fitting face mask unless eating or drinking. These visits may be conducted without physical distancing and include physical contact (e.g., hugs, holding hands) while in designated spaces for visitation that maintain 6-ft distancing between the visitor and facility staff and other residents they are not visiting; otherwise, visits between residents or visitors that are unvaccinated or incompletely vaccinated must be conducted with well-fitting face masks during the visit and maintain 6-ft physical distancing."

Q-3: For residents who received the booster, are they allowed to go to common areas without a mask?
A: No. There are no different infection control or masking requirements or allowances based on receiving the booster vaccine. The guidance around masking applies to the vaccination status from the primary series of the vaccine. The booster doesn't put an individual into a separate category with regard to other masking or infection control considerations.

Q-4: A newly admitted resident has their CDC vaccination card, but we cannot find them in the California Immunization Registry (CAIR2). How can we update CAIR2?
A: CAIR2 is a secure, confidential, statewide computerized immunization information system for California residents (https://cairweb.org/enroll-now/). Sometimes there may be data entry problems or delays and the immunization information cannot be accessed until those are corrected. To troubleshoot, individuals can utilize the CDPH Virtual Vaccination Support website: https://chat.myturn.ca.gov/?id=17. Another option is to contact the provider who administered the vaccine to ensure they input the correct information into CAIR2. If SNFs have access, they may be able to update the correct vaccine information directly into CAIR2. Another method to access vaccine records is using the Digital COVID-19 Vaccine Record (DCVR), but this system is tied directly to information in CAIR2 https://myvaccinerecord.cdph.ca.gov/. DCVR requires a match on email address or mobile phone number. Since many nursing home residents don't have either, they're unable to obtain their DCVR. Solutions include: 1) CDPH works with the nursing home to manually generate DCVR QR codes for staff to distribute to their residents; or 2) Nursing home staff validate residents' vaccination records by scanning QR code using the SMART Health Card Verifier app. For more information contact: DCVRRemediation.Requests@cdph.ca.gov.

Q-5: In a clinic, do staff need to disinfect chairs between individuals receiving the vaccine?
A: No. In general, disinfecting the chairs is not required in clinics between each individual receiving the vaccine, provided the chair has not been soiled or contaminated. It would be a good practice to periodically clean and disinfect the chair.

Q-6: For the Pediatric vaccine, if there is a child right around age 12, which vaccine is recommended?
A: Visit the CDC website to view the most updated information regarding vaccination of children and adolescents www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#children). Guidance on dosing and formulation for children was updated on November 3, 2021 and says, "Children should receive the vaccine dosage and formulation based on their age on the day of vaccination with each dose. If a child turns 12 years old between their first and second dose, they should receive the age-appropriate 30 µg Pfizer-BioNTech COVID-19 Vaccine (purple cap) formulation or COMIRNATY for their second dose to complete their series. However, the FDA authorization allows children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen to receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation for children aged 5–11 years (each 0.2 ml dose containing 10 µg in an orange cap vial); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 mcg in a purple cap vial). If such dosing occurred, the child is considered fully vaccinated. This is not considered an error and VAERS reporting is not indicated".

Q-7: On the CDPH daily 123 survey, is there a vaccination question that addresses the third dose or the booster dose?
A: Please refer to the CDPH Weekly Testing and Vaccination reporting data dictionary pages 5 and 6 where you will find questions on the booster and additional vaccine doses (https://www.cdph.ca.gov/Programs/CHCQ/LCP/CDPH%20Document%20Library/AFL-20-60-Attachment-01.pdf).

Q-8: What are the current guidelines related to booster doses following natural COVID infection in individuals who received the complete COVID vaccine series prior to natural infection? Do we need to wait >90 days post infection?
A: People with known current SARS-CoV-2 infection should defer vaccination at least until the person has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation. After discontinuing isolation, there is no minimum interval recommended before vaccination. The previously recommended 90-day time window after becoming infected with COVID-19 is no longer recommended by CDC.
However, the CDC recommends that the COVID-19 vaccination for people who have received anti-SARS-CoV-2 monoclonal antibodies be deferred until ≥90 days after the therapy is completed. This is a precautionary measure, as the mAb treatment may interfere with vaccine-induced immune responses.

Testing Questions & Answers

Q-9: Our Assisted Living resident tested positive on October 25, 2021. The dialysis center is requesting 2 negative tests before they can go to a non-isolation dialysis appointment. It is our understanding that we should not test the resident for 90 days from the positive test. Is that correct?
A: The requirement for two negative tests is inappropriate following a resident that has just recovered from COVID and is no longer in isolation. CDC guidance states that a COVID recovered individual should not be tested again for 90 days from the positive test because they may shed or have fragments of the virus that can give a positive test result. The test-based strategy for discontinuing isolation should only be used in rare situations. For assistance in educating your local dialysis center, engage your local health department, reference the CDC guidance, and contact your local End Stage Renal

Disease (ESRD) Network Contractor for assistance. You can contact HSAG, who serves as the ESRD contractor for Network 17 (Northern California) https://www.hsag.com/en/esrd-networks/esrd-network-17/ and Network 18 (Southern California) https://www.hsag.com/en/esrd-networks/esrd-network-18/.

Isolation & Quarantine Questions & Answers

Q-10: After an unvaccinated resident finishes their isolation period from being COVID recovered, can they be cohorted with fully vaccinated residents?
A: Yes. To clarify, CDPH does not recommend cohorting residents based on vaccination status. Cohorting should be done based on resident exposure status or infectious status. Based on this scenario, once the residents complete their isolation period and are COVID recovered, they can be cared for in the green zone, regardless of their vaccination status.

Q-11: If an HCP is asymptomatic and tests positive for COVID, but then develops symptoms 5 days later, when does the 10-day isolation period start? From the date of the positive test, or the day that symptoms started?
A: The 10-day isolation period begins on the date of symptom onset, even if the symptom onset is a few days after the positive test. If an individual remains asymptomatic, the date of the positive test would be the start of isolation. Also, note that there may be some instances in individuals with COVID-19 who have severe underlying immunocompromising conditions (such as receiving chemotherapy for cancer treatment) who may shed the virus for a prolonged period of time. In that case, isolation may need to be extended up to 20 days, or sometimes even longer. Consult with the provider managing the immunocompromising condition.

Q-12: When a yellow zone resident with a roommate has an indoor visit, is it safe for the roommate to leave the room during the visit, as long as they stay near the yellow zone?
A: CDPH recommends that roommates leave the room when there is an indoor visit occurring. It would be ideal to designate a specific room or place for a yellow zone resident to remain when their roommate is having a visit. This would only be acceptable if the roommate wears source control and it would be preferable for the roommate to be in a separate area where they are distanced from others.

Q-13: Two of our fully vaccinated staff live in the same household. One is COVID positive, and the other is negative and asymptomatic. What is the quarantine guidance?
A: In this scenario, we would assume that it would be difficult for the staff member that is negative to quarantine and have no exposure from the staff member living with them that is COVID positive. Since the negative staff member is fully vaccinated and asymptomatic, per AFL 21-08.5 (https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-08.aspx) they do not need to be restricted from work for 14 days following their exposure. However, if the staff member was unvaccinated, they should be excluded from work for 14 days in the absence of staffing shortages. Work restrictions for fully vaccinated HCP populations with higher-risk exposures should still be considered for HCP who have underlying immunocompromising conditions (e.g., organ transplantation, cancer treatment), which might impact level of protection provided by the COVID-19 vaccine. The 14 days would start after the COVID positive individual in their household finishes their 10-day isolation period. During critical staffing shortages, asymptomatic unvaccinated SNF HCP may return to work after Day 7 from the date of last exposure if they have received a negative PCR or other molecular test result from a specimen collected on Day 5 or later. Fully vaccinated asymptomatic HCP should have a series of two viral tests for SARS-CoV-2 infection. In these situations, testing is recommended immediately (but not earlier than 2 days after the exposure) and, if negative, again 5–7 days after the exposure (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-

hcp.html). If there is ongoing response testing, the fully vaccinated worker with a high risk exposure should continue to be included in the response testing schedule.

PPE Questions & Answers

Q-14: Do staff need to wear N95s when giving aerosolized treatments to fully vaccinated residents?
A: The guidance for universal use of respiratory protection during nebulizer or other potential aerosol-generating procedures (AGPs), is related to the amount of community transmission. The treatment can be done without staff wearing respiratory protection if the community transmission is low/minimal and the facility does not have suspected or confirmed COVID-19 cases; but the treatment should be avoided and/or respiratory protection should be used if the community transmission level is high or moderate. Work with your physicians and pharmacists to find other modes of medication administration if possible if your facility has an outbreak or if the community transmission level is high. Check with your local health department to determine your community transmission level.

Monoclonal Antibodies Questions & Answers

Q-15: Is there a waiting period required between COVID-19 vaccine and monoclonal antibody treatment?
A: The CDC recommends that SARS-CoV-2 vaccination for people who have received anti-SARS-CoV-2 monoclonal antibodies be deferred until ≥90 days after the therapy is completed. This is a precautionary measure, as the mAb treatment may interfere with vaccine-induced immune responses.

Q-16: Can anyone speak to why more doctors are not educated about the use of mAb?
A: There are a number of reasons why doctors are not using mAb, including the perceived lack of availability, changes in distribution points, and need for ongoing communication to physicians about current options and use. CDPH is using this forum and others for getting the word out. CALTCM's COVID webinar also covered this in a recent update and the recording is available if your physicians are CALTCM members. If your physicians are not members, please have them join our live webinar on Nov 8, 2021 which is FREE and they can ask questions during the Q&A. Register for free at www.CALTCM.org/Covid-19-webinars

Q-17: Any news on upcoming treatments besides monoclonal antibodies that may be easier to administer?
A: Molnupiravir is an oral antiviral made by Merck. It's currently not in use, but would be used to prevent high risk individuals with COVID-19 infection from developing severe disease and post-exposure prophylaxis. It appears to be less effective based on the early data we have seen compared to monoclonal antibodies. Also, AstraZeneca is producing another monoclonal antiviral that would last up to 12 months and provide long term protection. This would not be a replacement for the vaccine, but would be useful to individuals who can't get the vaccine or for those whose immune systems aren't responding to the vaccine. More information will be coming soon from the FDA later this month.

Q-18: Do skilled nursing facilities need an exemption to provide monoclonal antibodies?
A: An exemption (waiver) is not needed for nursing homes to provide monoclonal antibodies. It is a medication, just like any other medication that a physician would prescribe.

Anti-SARS-CoV-2 Monoclonal Antibodies

Refer to the November 1, 2021 CAHAN Disease Notification – "Anti-SARS-CoV-2 Monoclonal Antibodies" that describes the current recommendations for treatment and post-exposure prophylaxis use of anti-SARS-CoV-2 monoclonal antibodies. It outlines the available products for health care providers and directs them to additional information for proper use.

Background

Monoclonal antibodies that target the SARS-CoV-2 spike protein have been shown to provide clinical benefit in treating SARS-CoV-2 infected adults and pediatric (12 years of age and older weighing at least 40 kg) outpatients with mild to moderate symptoms who are at risk for disease progression. These treatments reduce the risk of progression to severe disease, hospitalization, and death in high-risk populations[1].

Additionally, some of these anti-SARS-COV-2 monoclonal antibody products can be used as post-exposure prophylaxis (PEP) in high-risk populations and can be dosed monthly when there is ongoing exposures in high risk institutional settings (for example, nursing homes and prisons).
The currently available anti-SARS-CoV-2 monoclonal antibodies that have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) and are available for use in California include:

- Bamlanivimab/etesevimab[2] – This product is administered intravenously and approved for use as a treatment or as a post-exposure prophylaxis
- Casirivimab/imdevimab[3] (REGENCOV) – All available forms of casirivimab/imdevimab may be administered **either subcutaneously** or by IV infusion. Instructions for preparation for each route of administration can be found in the Dosage and Administration section of the product EUA. Approved for use as a treatment or as a post-exposure prophylaxis.
- Sotrovimab[4] – This product can be administered intravenously and is approved for use as a treatment.

Providers using these products should carefully review the EUAs[1,2,3] for treatment criteria, dosing, and administration guidance. The approval of a subcutaneous route of administration for casirivimab/imdevimab as of June 2021 provides an alternative to IV administration and should decrease barriers to use.

These drugs are currently not approved for use as pre-exposure prophylaxis, nor should they be used as replacements for vaccination.

Product	Indications	Coverage of Variants Circulating in California	Administration	Acquiring Product
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

[1] As listed in product EUAs with additional detail here: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html
[2] https://www.fda.gov/media/145802/download
[3] https://www.fda.gov/media/145611/download
[4] https://www.fda.gov/media/149534/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
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

Use Post-Exposure Prophylaxis

Bamlanivimab/etesevimab and casirivimab/imdevimab are approved for use in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19. Use as post-exposure prophylaxis should be considered in individuals who are at high risk of 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) and
    - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria[5] per Centers for Disease Control and Prevention (CDC); or
    - who 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 example, nursing homes and prisons).

For individuals in whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2, these products can be administered every 4 weeks for the duration of ongoing exposure. Further criteria and instructions for dosing in these scenarios can be found in the product EUAs.

Distribution of Anti-SARS-COV-2 Monoclonal Antibody Products to Facilities

Due to national shortages, the U.S. Department of Health and Human Service (HHS) is allocating courses weekly of all three drugs to U.S. states and territories based on COVID-19 case counts and hospitalizations for the preceding week[6]. The California Department of Public Health (CDPH) allocates product to local jurisdictions based on numbers of new COVID-19 cases and COVID-19 hospital admissions, both expressed as a 7-day average.

Once the number of patient courses has been allocated, local health departments and each jurisdiction's Medical and Health Operational Area Coordinator (MHOAC) will assist in determining which facilities within their jurisdiction receive product. Facilities that would like to obtain product or require more product should contact their MHOAC[7].

Considerations Given Potential Logistical and Supply Constraints

While need for anti-SARS-CoV-2 monoclonal antibodies may increase or decrease depending on COVID-19 prevalence, susceptibility of circulating SARS-CoV-2 variants to specific monoclonal antibody products, patient demand, and other factors, there may be times when logistical or supply constraints exist for anti-SAS-COV-2 monoclonal antibody products.

When supplies are not constrained at facilities, providers should use anti-SARS-COV-2 monoclonal antibody products as both treatment and post-exposure prophylaxis as outlined in the product EUAs.

[5] https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html
[6] https://www.phe.gov/emergency/events/COVID19/therapeutics/distribution/Pages/data-tables.aspx
[7] https://emsa.ca.gov/wp-content/uploads/sites/71/2021/09/MHOAC-Contact-List-9.2.2021-Public.pdf

In situations of logistical or supply constraints, priority for providing anti-SARS-COV-2 monoclonal antibody products to patients at high risk for progression to severe COVID-19 should be considered for two uses: 1) treatment over use as post-exposure prophylaxis, and 2) use for patients not fully vaccinated or patients not expected to mount a sufficient immune response according to CDC guidance.

Individual clinical situations vary and use depends on clinical judgment. Useful considerations for prioritizing use of anti-SARS-COV-2 monoclonal antibodies while constraints are present can be found at the National Institutes of Health's COVID-19 Treatment Guidelines website[8].

Activity Against Variants

Casirivimab/imdevimab (REGEN COV), bamlanivimab/etesevimab, and sotrovimab have activity against the variants currently circulating in CA, including the current sub-lineages of Delta in circulation.

The Delta sublineages AY.1 and AY.2 (which include the mutation K417N) are resistant to bamlanivimab/etesevimab. Currently these resistant sublineages make up a very small proportion of circulating virus in the United States, data on October 29, 2021, show that AY.1 and AY.2 together make up <1% of circulating variants in California[9].

The FDA does not authorize use of bamlanivimab/etesevimab in any state where resistant variants to this product exceed 5%. The FDA maintains a list of states and territories where resistant strains are circulating, and this page should be reviewed by healthcare providers using this product[10].

As of October 29, 2021, bamlanivimab/etesevimab is approved for use in all U.S. states and territories, and providers should continue to use this therapy at this time.

Additional Resources

For facilities and healthcare providers interested in setting up infusions for high-risk patients with COVID-19, the Assistant Secretary for Preparedness and Response (ASPR) has many resources available[11]. This includes free digital content[12] that your facility can use on social media platforms to help educate providers and patients. HHS has also established the CombatCovid website[13] as a resource for patients and providers.

Reporting of 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. Full reporting details as well as a link providing detailed instructions on how to access each reporting tool can be found on the Reporting Utilization of COVID-19 Therapeutics website[14].

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 Porta

[8] https://www.covid19treatmentguidelines.nih.gov/therapies/updated-statement-on-the-prioritization-of-anti-sars-cov-2-mabs/
[9] https://covid.cdc.gov/covid-data-tracker/#variant-proportions
[10] https://www.fda.gov/media/151719/download
[11] https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx
[12] https://www.phe.gov/emergency/events/COVID19/therapeutics/toolkit/Pages/default.aspx
[13] https://combatcovid.hhs.gov/
[14] https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx