



**California Department of Public Health
Weekly Facility COVID-19 Update Call
November 24, 2020
8:00 am – 9:00 am**

AT&T Meeting Recording: 1 (866) 207-1041

Access Code: 8006241

Available after 7pm 11/24/2020

- | | |
|---|------------------------------|
| I. Welcome / Introduction | Heidi Steinecker |
| II. Overview | Dr. Kathleen Jacobson |
| • None Provided | |
| III. Laboratory Update | Dr. Jill Hacker |
| • No update this week – available for questions | |
| IV. COVID Vaccine | Nisha Gandhi |
| • No update this week – available for questions | |
| V. Healthcare-Associated Infections | Dr. Erin Epton |
| 1. Today, we anticipate posting of a new AFL on Movement of Patients/Residents in the Healthcare Continuum During Seasonal Surges and the COVID-19 pandemic. As we move into the influenza season with the co-occurrence of COVID-19, anticipated surges in hospital admissions and emergency department visits can affect hospital capacity when skilled nursing facilities (SNFs) do not accept new admissions or readmissions of residents from hospitals. | |

The purpose of this AFL is to clarify considerations for SARS-CoV-2 testing and quarantine of new SNF admissions, management of readmissions and for limitations on new admissions during an outbreak.

SARS-CoV-2 testing and quarantine in the yellow-observation area for new admissions to SNF to monitor the resident for 14 days since the date of their last likely potential exposure outside the SNF, which could be in the community or in the transferring healthcare facility if that facility is having an outbreak. SNF should refer to [AFL 20-74](#) and [AFL 20-80](#) for guidance on resident placement and cohorting based on COVID-19 and influenza status. The 2 tests 24 hours apart test-based strategy is not a strategy for screening asymptomatic new admissions whose COVID status is unknown. SNFs may not require two negative tests 24 hours apart for screening of new admissions. One screening test collected during the hospitalization within 48 hours of discharge date is sufficient. SNF residents hospitalized and requiring transmission-based precautions for COVID-19 or influenza should be discharged from the acute care setting when clinically appropriate, not

based on the period of potential virus shedding or recommended duration of transmission-based precautions. SNFs must prepare for and have the necessary staffing and PPE supplies available to implement transmission-based precautions as needed for residents re-admitted after hospitalization.

Regarding limitations on new admissions to SNF during an outbreak, demonstration of containment with two sequentially negative rounds of response testing should not be the sole basis for determining closures to new admissions. Particularly during hospital surges, LHD should consider the following factors to allow flexibility for SNFs to continue admitting new residents before outbreak containment is demonstrated:

- SNF has implemented outbreak control measures, as appropriate, such as response testing, cohorting, dedicated staff for the COVID-19 positive zone with no crossover, transmission-based precautions, and chemoprophylaxis (for influenza, assuming adequate availability)
 - SNF has no staffing shortage or operational problems (e.g., administrator or director of nursing out sick). SNF must have a trained infection preventionist. Long term staffing plans should be documented.
 - SNF has adequate personal protective equipment (PPE), staff from all shifts have access to N95 respirator fit testing and all staff have been fit-tested to the respirator model(s) currently available for use in the facility, and access to adequate hand hygiene and environmental cleaning supplies
 - SNF has a well-demarcated “yellow” COVID-19 observation area (unit or wing) for new admissions
2. CDC added a new question on HCP exposed to a COVID-19 case at home on their [COVID Healthcare IPC FAQ webpage](#):

Question: “If healthcare personnel (HCP) are living with someone who has been diagnosed with SARS-CoV-2 infection, should they be excluded from work? If so, for how long?”

Answer: Yes. In general, HCP who have any kind of [exposure](#) for which [home quarantine](#) is recommended should be excluded from work:

- If HCP are able to quarantine away from the infected individual living with them, they should quarantine at home and not come into work for 14 days following their last exposure to the infected individual. HCPs who are [excluded from work due to an exposure](#) should stay away from others in the community setting per the community guidance
- If HCP are not able to quarantine away from the infected individual living with them and have ongoing unprotected exposure throughout the duration of the individual’s illness, they should remain in home quarantine and be excluded from work until 14 days after the infected individual meets [criteria for discontinuation of home isolation](#).
- If HCP develop SARS-CoV-2 infection while they are in quarantine, they should be excluded from work until they meet all [return to work criteria](#) for HCP with SARS-CoV-2 infection.

Home quarantine and work exclusion of asymptomatic exposed HCP who have recovered from SARS-CoV-2 infection in the prior 3 months might not be necessary.

When staffing shortages are anticipated or occurring, healthcare facilities may need to implement [contingency and crisis capacity strategies for mitigating staffing shortages](#) to continue to provide patient care. Contingency strategies allow asymptomatic HCP who have had an [unprotected exposure](#) to SARS-CoV-2 but are not known to be infected to continue to work. When testing is readily available, performing post-exposure testing during the 14-day post-exposure period can be considered to more quickly identify pre-symptomatic or asymptomatic HCP who could contribute to SARS-CoV-2 transmission. While some HCPs might [continue to work in the healthcare setting](#) after an exposure, these individuals should still stay away from others when in the community setting per the community guidance.

3. [CDC infection control guidance](#) on facemasks:

"HCP should wear a facemask at all times while they are in the healthcare facility, **including in breakrooms or other spaces where they might encounter co-workers.**

- **When available, facemasks are preferred over cloth face masks for HCP** as facemasks offer both source control and protection for the wearer against exposure to splashes and sprays of infectious material from others.

Facemask: Facemasks are PPE and are often referred to as **surgical masks or procedure masks.** Use facemasks according to product labeling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Facemasks that are not regulated by FDA, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays."

VI. Remdesivir Update

Dr. Philip Peters

1. Casirivimab / Imdevimab EUA

On November 21, 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for another investigational monoclonal antibody therapy for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. The new investigation monoclonal antibody product is a combination of two monoclonal antibodies called casirivimab and imdevimab.

The EUA allows healthcare providers to administer casirivimab and imdevimab to non-hospitalized patients with confirmed COVID-19 who are experiencing mild to moderate symptoms and are at high-risk for severe symptoms and hospitalization.

The EUA was based on results from a phase 1/2 clinical trial that has not been published but is referenced in the EUA. In this trial, the combination of casirivimab and imdevimab was shown to reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for severe disease. Importantly, casirivimab / imdevimab is authorized only for outpatient use and is not authorized for patients who are hospitalized due to COVID-19 or who require oxygen therapy due to COVID-19. In another randomized controlled trial, the combination of casirivimab and imdevimab was associated with a potential safety signal and an unfavorable risk/benefit profile in patients requiring high-flow oxygen or mechanical ventilation.

A few Clinical and logistical details: Monoclonal antibodies are created in a lab to bind to SARS-CoV-2's receptor binding domain and neutralize the virus.

- Authorized for use to treat of mild-to-moderate COVID-19 in adult and pediatric (at least 12 years of age and weighing at least 40kg) patients who met high-risk criteria specified in the EUA for progression to severe disease.
- May only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis.
- Intravenous (IV) infusion of 1,200 mg of casirivimab and 1,200 mg of imdevimab combined together and administered over at least 60 minutes as soon as possible after positive viral test for SARS-CoV2 and within 10 days of symptom onset.
- Clinically monitor patients during infusion and observe patients for at least one hour after infusion.
- Refrigerate unopened vials at 2°C to 8°C in the original carton to protect from light.
- Instructions to prepare casirivimab and imdevimab for infusion are included in the EUA.
- Product is donated (no cost to state or clinical sites) but **costs for infusion services** would need to be covered by insurance or another mechanism.
- Operation Warp Speed and ASPR will determine allocations to states and have stated that in phase one AmerisourceBergen **will distribute donated product to hospitals only** although the infusions would have to be given in non-hospitalized settings such as emergency departments, urgent care, and ambulatory centers that are able to administer this medication.
- We are likely to receive details by Wednesday morning regarding how much of this product will be allocated to California and facilities will start to receive this medication over the weekend or next.

Links to the EUA including information for healthcare providers and patients is included in the meeting notes.

FAQ: <https://www.fda.gov/media/143894/download>

Fact sheet for health care providers: <https://www.fda.gov/media/143892/download>

Fact sheet for patients, parents, and caregivers: <https://www.fda.gov/media/143893/download>

2. **Bamlanivimab allocations**

Link for further information: <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Bamlanivimab-Fact-Sheet.aspx>

Fact sheet for healthcare providers: <https://www.fda.gov/media/143603/download>

For week two, California received an allocation of 2,250 doses which was about half of the amount that we had received in week one. CDPH is using acute care hospital data of the 7-day average of new COVID-19 admissions and conversions to proportionately distribute bamlanivimab to the counties' Medical and Health Operational Area Coordinator (MHOAC) per the established Multi-Agency Coordination Group (MAC Group) process. The MHOAC then allocates bamlanivimab within their county to hospitals (phase 1) and other facilities (phase 2). Based on this allocation bamlanivimab is shipped to hospitals by AmerisourceBergen. Details on the week one allocation

are here: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CA-Bamlanivimab-Allocation_11-13-20.xlsx

CDPH recommends prioritizing patients who had the greatest benefit in the clinical trial: patients who are > 65 years of age and patients with a body mass index (BMI) > 35. This prioritization includes residents of skilled nursing facilities (SNFs) and other long-term care facilities who receive regular testing for COVID-19 and are at high risk for severe COVID-19 illness.

3. **Clinical treatment recommendations**

Both the NIH and the IDSA released recommendations for bamlanivimab in the context of the EUA approval.

The NIH guidelines stated that at this time, there are insufficient data to recommend either for or against the use of bamlanivimab for the treatment of outpatients with mild to moderate COVID-19. Bamlanivimab should not be considered the standard of care for the treatment of patients with COVID-19. Patients at highest risk for COVID-19 progression should be prioritized for use of the drug through the EUA.

NIH COVID-19 Treatment Guidelines: <https://www.covid19treatmentguidelines.nih.gov/whats-new/>

IDSA COVID-19 Treatment Guidelines: <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-10>

4. **Bamlanivimab allocations plans in future**

CDPH is exploring options to broaden the distribution of bamlanivimab to non-hospital settings that can infuse medication. Skilled nursing facilities (SNFs) have been identified as a priority non-hospital settings as residents are: (i) in the population with the highest potential benefit, (ii) tested frequently resulting in early diagnoses, and (iii) physically residing at a location that can provide an immediate infusion. We are looking at an allocation model where some of the bamlanivimab allocation would be provided to specialty pharmacies as a limited number of specialty pharmacies serve the majority of SNFs in California. In this proposed model, if a SNF is able to provide an infusion, they could order bamlanivimab from their specialty pharmacy who would compound the product and send to the SNF for infusion. It is expected that the SNF utilization will initially be low and then increase. Given the high mortality of COVID-19 among SNF residents in California to date, an attempt would be made to meet the need in this setting.

VII. **Questions and Answers**

Q: When will the COVID vaccine enrollment be available for skilled nursing facilities?

A: The vaccine needs to be stored in ultra-low temperatures and that is limiting the number of partners. We do plan to roll out enrollment further out to ensure that all facilities have access to the vaccine and vaccinators if needed.

Q: About the antibody injections in SNF, are they for residents or could that be for the healthcare workers working in the SNF as well?

A: It's a relatively scarce resource. We want to be as data driven as possible when it comes to the antibody injections since they are so limited. I'm sure if there was some occupational health risk that they would receive a treatment on site, that would work as a protocol.

Q: There are guidances coming out from various health department encouraging the use of multiplex respiratory panel when other viruses on that panel, are not treatable and the actual influence that they might have on a patient course for someone who's otherwise been healthy is totally unclear. Can you speak on that?

A: We indicated that in situations in a Skilled Nursing Facility where there is an outbreak, this could potentially be used in a setting where both COVID-19 and influenza testing are negative. A broader respiratory panel could be used in that situation.

Q: Can you speak on the requirement for medical grade masks only for healthcare personnel as long as they are in the healthcare facility? Can you clarify what you mean by medical grade? Is every worker in the hospital considered a healthcare personnel regardless of what they are doing?

A: Healthcare personnel need to wear a medical grade facemask for source control instead of the cloth facemask as the cloth facemask as they are not well studied, document or consistent.

Q: Are you planning to provide more formal messaging regarding this?

A: We can look back at the AFLs and add clarifications on the messaging.

Q: It was mentioned that acute care facilities at this stage would be enrolling for vaccines. Do inpatient psychiatric hospitals fall into that enrollment?

A: Yes you can complete the enrollment.

Q: Is there a threshold to say that we are in a staffing shortage and what does the state recommend as proof of exposure? Does the healthcare facility require the healthcare personnel to prove that they have been exposed? Will there be an AFL coin got address these new expectations for asymptomatic healthcare workers?

A: We have ratios in California for threshold ratios. It up to facilities to do their due diligence but we encourage facilities to work with local registries and whatever staffing contracts that you typically work through first to ensure that you have staff on hand. As for exposure, there is some information on the on the CDC guidance on what staff are able to work and have the option to work if they are positive.

Q: About the asymptomatic exposed worker who we would be bringing back into work due to staffing contingencies, you mentioned that we may opt to do serial testing. Is nasal swab an acceptable alternative MP in that situation?

A: MP is the most sensitive specimen type.

CANCELLED!!! Wednesday, November 25 Webinar: 3-4pm
CANCELLED!!! Thursday, November 26 SNF IP 12pm Call