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CALTCM.org

Webinar Series

COVID-19: CALTCM Weekly Rounds

November 16, 2020

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Janice Hoffman-Simen, Pharm.D., EdD, APH, BCGP, FASCP
Ashkan Javaheri, MD
Albert Lam, MD
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Karl Steinberg, MD, CMD, HMDC
Michael Wasserman, MD, CMD



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November 30
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Housekeeping

- **To help keep background noise to a minimum, please mute your microphone when you are not speaking.**
- We invite you to turn on your camera and unmute your line to ask questions and participate in the discussion.
 - Feel free to raise your hand when you have a question.
 - Please do not talk over others.
- **Review your name** and make any necessary adjustments.
- **Close all other windows and apps**, especially mail and messaging programs.


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Webinar Faculty

Terri Ballesteros
Administrator
Manor Care Health Services



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Webinar Faculty

Jay Luxenberg, MD
Chief Medical Officer, On Lok
CALTCM, Wave Editor-in-Chief



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Webinar Faculty

Phillip Peters, MD
Medical Officer, California Department of
Public Health; CDPH's Antiviral Lead;
Therapeutics and Vaccine work group
Chair, Medical Advisory Committee,
California's AIDS drug assistance program
(ADAP) and the Clinical Quality Management
Committee for California's Ryan White Part B
program.



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Moderator & Webinar Faculty

Karl E. Steinberg, MD, CMD, HMDC
President-Elect, AMDA: The Society for Post-Acute and Long-Term Care Medicine; CALTCM BOD Member; Chief Medical Officer, Mariner Health Care; Past Chair, Coalition for Compassionate Care of California




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Webinar Faculty

Michael Wasserman, MD, CMD
Geriatrician, Medical Director, Eisenberg Village, Los Angeles Jewish Home
CALTCM, Immediate Past President and Chair, Public Policy Committee



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**COVID-19 Vaccine & Treatment:
Trials & Distribution**



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Monoclonal Antibody Emergency Use Authorization – Review of Allocation of Bamlanivimab in California

Philip Peters, MD
Medical Officer
California Department of Public Health

Many slides adapted from the Operation Warp Speed
Monoclonal Antibody Playbook



<https://www.cdph.ca/emergency/preventive/COVID-19investigation>
<https://www.cdph.ca/emergency/preventive/COVID-19investigation>

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About Monoclonal Antibodies

Monoclonal antibodies (mAbs) directly neutralize the
COVID-19 virus and are intended to **prevent progression
of disease**

mAbs likely to be most effective when **given early in
infection**

Product delivered via **single administration (e.g., IV
infusion)**

Early evidence suggested promise of mAb products in
outpatient settings

- Early evidence from Eli Lilly mAb **showed potential
to reduce hospitalization** for infected people if given
early in infection in BLAZE-1 clinical trial
- FDA granted **Emergency Use Authorization** for
bamlanivimab on November 9, 2020

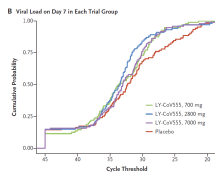
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Bamlanivimab Clinical Trials to Date

BLAZE-1 clinical trial [1]: 465 non-hospitalized adults

• Secondary analysis of hospitalization or ER visit:

- Bamlanivimab: 1.6%
(4.2% age ≥ 65 or BMI ≥ 35)
- Placebo: 6.3%
(14.6% age ≥ 65 or BMI ≥ 35)



ACTIV-3 clinical trial [2]: 326 hospitalized participants

• Bamlanivimab was discontinued as not beneficial



Chen P, Nirula A, Heller B, et al. SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19. *NEJM*. Electronically published: October 28, 2020. DOI: 10.1056/NEJMoa2026849
NIH Press Release: Statement—NIH-Sponsored ACTIV-3 Trial Shows LY-CoV555 Sub-Study. October 28, 2020

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Bamlanivimab Clinical Indications

- Treat mild to moderate outpatient treatment
 - **Not asymptomatic and not hospitalized**
 - High risk for severe illness including BMI \geq 35, chronic kidney disease, diabetes, immunosuppression, or age \geq 65 years. Additional criteria for \geq 55 years and for people 12 – 17 years
- Treat early – within 3 days of positive test (median 4 days from symptom onset in clinical trial)
- Administered by intravenous (IV) infusion over 60 minutes
- Mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths



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

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Two Phases of Allocation

- **Phase 1:** States and territories allocate bamlanivimab to hospitals and hospital-affiliated locations only
- **Phase 2:** States and territories allocate to outpatient facilities
 - Urgent care clinics
 - Outpatient office
 - Patient home via telemedicine / home health service
 - Community sites / temporary tents
 - Nursing home

Alternate site of care will need same core capabilities and supplies as typical site of administration



https://www.hhs.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Documents/OWS_MAB_%20playbook_10Nov20-508.pdf

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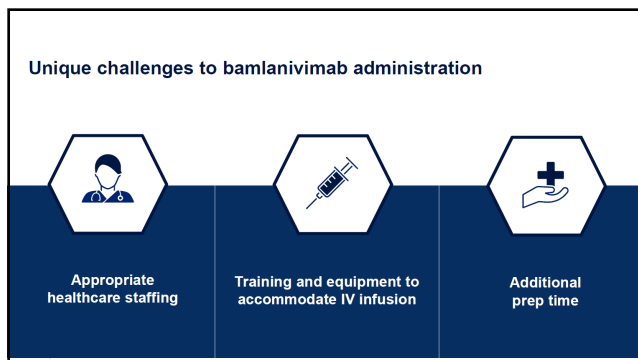
Bamlanivimab Allocations in California

- Week 1: 4040 vials allocated to California
- Weekly allocations expected
- 1 vial = 1 dose = 1 treatment course
- Delivery for week 1 to acute care hospitals
- Allocation based on 7-day hospitalizations of COVID-confirmed patients by county
- Allocations to be posted on the CDPH COVID guidance page: <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx>

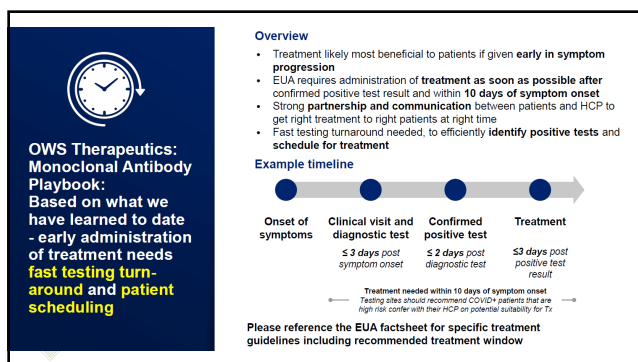


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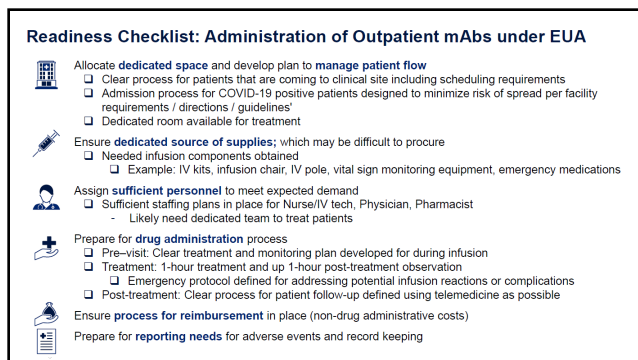
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- Alice Chen (CHHS)
- Tom Ahrens (CDPH)
- Jessica Khouri (CDPH)
- John Redd (ASPR)

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Q & A



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