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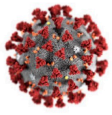
California Association of Long Term Care Medicine



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Webinar Series

COVID-19: CALTCM Weekly Rounds

January 11, 2021

1

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To request a copy of our 501(c)(3) status letter or current Form W-9, please contact the CALTCM Executive Office at (888) 332-3299 or e-mail: info@caltcm.org

2

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5

Housekeeping

- **To help keep background noise to a minimum, please mute your microphone when you are not speaking.**
- Please feel free to submit your questions in the chat box.
- During Q&A, you are invited to unmute your line to ask questions and participate in the discussion.
  - **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 Moderator

Janice Hoffman-Simen, Pharm.D., EdD, APh, BCGP, FASCP
Director, Postgraduate Residency Program, Jewish Home for the Aging; Associate Professor of Pharmacy Practice and Administration; Western University of Health Sciences

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Webinar Faculty

Jay Luxenberg, MD
Chief Medical Officer, On Lok
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Webinar Faculty

Sohrab Sidhu, MD, MPH
Medical Quality Officer, Office of the Medical Director (OMD) and COVID Therapeutics Task Force, California Department of Health Care Services

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Webinar Faculty

Michael Wasserman, MD, CMD
Geriatrician,
Immediate Past-President and
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Webinar Faculty

Chad Worz, PharmD, BCGP
Chief Executive
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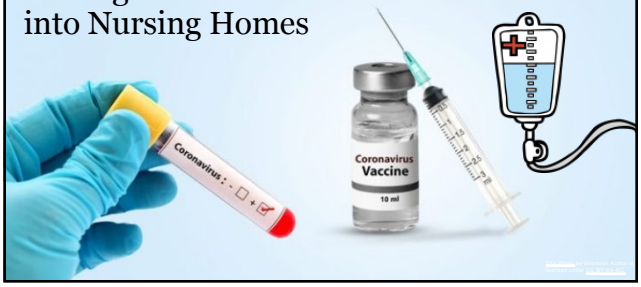
11

Making it Happen:
Getting Vaccines & IV Treatments into Nursing Homes



12

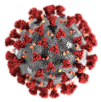
The COVID-19 Vaccine:
The Final Step for Long Term Care

Michael Wasserman, MD, CMD
Immediate Past President
California Association of Long Term Care Medicine

13

Kirkland, Washington Outbreak

- What we knew
  - Virus was deadly to vulnerable older adults
  - Evidence of asymptomatic spread
  - Nursing home staff as vector
  - Need for infection prevention and control measures
- Nursing homes, assisted living facilities and group homes were immediately afraid!
  - Most likely made an immediate difference
  - Unfortunately, not enough



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14

CALTCM's Long Term Care Quadruple Aim For COVID-19 Response

- Abundant PPE
  - Pandemic supply chain challenges
- Readily Available Testing
  - Need to detect asymptomatic and presymptomatic
- Stellar Infection Control
  - Need for Full-time Infection Preventionist
- Facility working under Emergency Preparedness/Pandemic Plan
  - Proxy for excellent leadership

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5th Element: COVID-19 Vaccine

- Evidence in older adults very positive
  - Albeit no clinical trials in nursing home residents
  - Would have been an excellent opportunity to perform clinical trials in nursing homes and assisted living facilities
- Opportunity to reduce spread from staff

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Long Term Care is a Unique Environment

- Long history of challenges in shaping quality of care
- Nursing homes are now “mini-hospitals”
- Assisted living facilities are not medicalized
- Group homes are a rapidly growing and unique milieu
- Much of the senior housing industry is focused on real estate

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17

Average Nursing Home

- $10 million/year business
- Residents are most complex in our history
- Front line staff with minimal education
- Nursing home administrators with limited education and training
- Directors of nursing with limited leadership and management training
- Medical directors rarely engaged

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18

Nursing Homes

- Focus typically on admissions, discharges, bottom line, not quality of care
- Weak leadership may be by design to increase malleability
- "Rule followers"
  - Fear of deficiencies
  - Fear of standing out
  - Both of these have become major issues during the pandemic

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19

Nursing Home Pharmacy Structure

- Every nursing home and assisted living facility in the country works with a contracted long term care pharmacy
  - Existing relationship
  - Existing distribution chain
  - Longstanding understanding of nursing home workflow
- Every nursing home has a consultant pharmacist
  - Independent contractor or employed by long term care pharmacy
  - Existing relationship
  - Relationship with staff

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Federal Pharmacy Partnership

- CVS and Walgreens
  - Did not take advantage of Omnicare and Pharmerica
  - 3 "Clinics"
  - Inappropriate consent form
  - No preceding relationships with facilities
  - No preparation for vaccine hesitancy
- "Pharmacy-centric"
  - Onus on facility for signing up and preparation
- Processes ultimately pushed down to state and county levels
- Didn't approach from "lowest common denominator"

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Vaccine Confidence

- Residents
  - Thankfully, vaccine confidence amongst residents and families appears high
  - Challenges in getting consent in cognitively impaired
  - Challenges in providing consent for unrepresented
- Staff
  - Much greater issue
  - Historically not surprising
  - Long history of vaccine hesitancy with influenza vaccine

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Solutions

- Immediately engage all contracted Long Term Care Pharmacies and consultant pharmacists to collaborate and assist in vaccination efforts
- Streamline "paperwork," make it facility, resident and staff "centric"
- Provide clear direction on appropriateness of verbal consent
  - Facilities can't be concerned about survey repercussions
- Train nursing home leadership, including the medical director, to provide effective education to improve vaccine confidence

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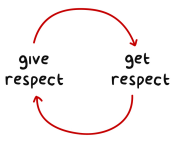
23

Best Practice: Town Halls
"*Respect, Honor & Value*"

- If possible, focus first "town hall" session on allowing staff to share their concerns
- It is critical that staff knows that you are *HEARING* their concerns
- Demonstrate that their concerns are being heard
- Do not try to correct concerns
- Have multiple town halls, to allow time to digest information



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24

Monoclonal Antibody Emergency Use Authorization –
Review of Clinical Indications and Allocation in California

Sohrab Sidhu, MD, MPH
Medical Quality Officer, Office of the Medical Director
California COVID Therapeutics Task Force
California Department of Health Care Services

Many slides adapted from Operation Warp Speed Monoclonal Antibody Playbook
https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Documents/OWS_MAB_%20playbook_10Nov20-508.pdf

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25

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

14

26

Emergency Use Authorizations (EUAs) for bamlanivimab and casirivimab/imdevimab

1. Positive direct SARS-CoV-2 test (e.g., PCR, rapid antigen test)
2. As soon as possible after positive test, within 10 days of symptom onset
3. In patients at high risk
4. Provider reviews EUA fact sheet; patient/caregiver provided with EUA fact sheet
5. Administered in a setting where HCPs have direct access to medications to manage severe reactions

27

Emergency Use Authorizations High-Risk Criteria

- All Patients (who meet at least 1 of the following criteria):
  - BMI ≥35
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease
  - Receiving immunosuppressive treatment
  - Age ≥ 65 years
  - Age ≥ 55 years AND have any of the following
    - Cardiovascular disease
    - Hypertension
    - COPD/other chronic respiratory disease
- Adolescents (Age 12-17 years) who meet at least 1 of the following criteria:
  - BMI ≥85th percentile for age/gender
  - Sickle cell disease
  - Congenital or acquired heart disease
  - Neurodevelopmental disorders (e.g., cerebral palsy)
  - Medical-related technological dependence [e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)]
  - Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

16

28

mAb Clinical Indications

- Mild to moderate outpatient treatment
  - **Not asymptomatic, not hospitalized and not requiring O2 (or increased baseline O2) due to COVID**
  - High risk for severe illness including BMI ≥ 35, chronic kidney disease, diabetes, immunosuppression, or age ≥ 65 years. Additional criteria for ≥ 55 years and for people 12 – 17 years
- **Treat early** – within 10 days of symptom onset (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

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

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29

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

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[1] 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/NEJMoa2029849
[2] NIH Press Release, Statement—NIH-Sponsored ACTIV-3 Trial Closes LY-CoV555 Sub-Study, October 26, 2020.

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30

Casirivimab / Imdevimab Clinical Trials to Date

- Outpatient 2067 clinical trial - 799 non-hospitalized adults with mild to moderate COVID-19 symptoms
  - The primary study outcome was the change from baseline in viral load and the decline in viral load was significantly larger at day 7 with casirivimab/imdevimab treatment.
  - Secondary analysis of hospitalizations or ER visit
    - Casirivimab/imdevimab: 1.8% (2.6% with one risk factor for severe illness)
    - Placebo: 4.3% (9.0% with one risk factor for severe illness)
- Hospitalized patient trial: Based on a potential safety signal and an unfavorable risk/benefit profile, enrollment of hospitalized patients requiring high-flow oxygen or mechanical ventilation was suspended. **Hospitalized patients who require no or low-flow oxygen can continue to enroll in the trial.**

[1] Fact Sheet for Health Care Providers - Emergency Use Authorization (EUA) of Casirivimab and Imdevimab. Available at: https://www.fda.gov/media/143892/download

[2] Regeneron Press Release. REGN-COV2 Independent Data Monitoring Committee Recommends Holding Enrollment in Hospitalized Patients with High Oxygen Requirements and Continuing Enrollment in Patients with Low or No Oxygen Requirements. October 30, 2020.

31

Overall Safety Summary

Bamlanivimab

Table 2: Treatment-emergent Adverse Events Reported in at Least 1% of All Subjects in BLAZE-1

Preferred term	Placebo N=156 %	Bamlanivimab			
		700 mg N=101 %	2,800 mg N=107 %	7,000 mg N=101 %	Total N=309 %
Nausea	4%	3%	4%	5%	4%
Diarrhea	5%	1%	2%	7%	3%
Dizziness	2%	3%	3%	3%	3%
Headache	2%	3%	2%	0%	2%
Pruritus	1%	2%	3%	0%	2%
Vomiting	3%	1%	3%	1%	2%

Casirivimab / Imdevimab

Infusion-related reactions of grade 2 or higher severity were reported in **1.5% of patients** and included pyrexia, chills, urticaria, pruritus, abdominal pain, and flushing.

One anaphylactic reaction has been observed with casirivimab/imdevimab. It resolved with treatment including epinephrine.

32

Monoclonal Products: Two Phases of Allocation

- **Phase 1:** states and territories allocate these products to hospitals and hospital-affiliated locations only
- **Phase 2:** states and territories allocate to outpatient facilities
  - Skilled Nursing Facilities and the PACE program
  - Urgent care clinics
  - State hospitals
  - State prisons
  - Community sites / temporary tents

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

CALTCM https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Documents/OWS_MAB_%20playbook_10Nov20-508.pdf January 11, 2021

33

12/28/20: Currently, California has a sufficient supply of monoclonal antibodies for all providers who request them

- HHS/ASPR is also strongly encouraging states/territories to use the monoclonal products and to not stockpile or hesitate to use based upon perceived scarcity.
- Should any facilities in California need more monoclonal product, they should contact as soon as possible their county's Medical and Health Operational Area Coordinators (MHOACs) according to local policies and procedures.
  - If the MHOAC programs do not have any product, the MHOACs should make a request at the regional level, to the Regional Disaster Medical Health Coordinators (RDMHS). The RDMHS can check with other MHOAC programs and if the RDMHS is unable to obtain the necessary quantities, the resource request will move to the state. If the state has product in stock, the state will fill the request.

34

Skilled Nursing Facilities (SNFs), PACE programs and State Prisons Prioritized

SNFs, PACE programs and state prisons are potentially optimal non-hospital settings for bamlanivimab treatment as the vast majority of residents are:

- in the age group and/or with high-risk medical conditions with the highest potential benefit
- tested frequently, resulting in early diagnoses
- physically residing at or close to a location that can potentially provide an immediate infusion

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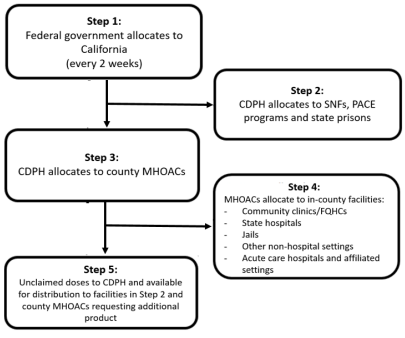
35



36

mAb Allocations for California

- Week 1: 4,040 vials Bamlanivimab
- Week 2: 2,250 vials Bamlanivimab
- Week 3: 3,230 vials Bamlanivimab
  - And 2,328 doses Casirivimab/Imdevimab
- Week 4: 3,040 vials Bamlanivimab
  - And 2,160 doses Casirivimab/Imdevimab
- Week 5: 4,450 vials Bamlanivimab
  - And 1,240 doses Casirivimab/Imdevimab
- Week 6: 6,420 vials of Bamlanivimab
  - And 1,380 doses Casirivimab/Imdevimab
- Weeks 7-8*: 14,020 vials of Bamlanivimab
  - And 4,080 doses Casirivimab/Imdevimab

* Federal allocation changed from weekly to once-every-two-weeks starting in Week 7.

1 vial = 1 dose = 1 treatment course

California Monoclonal Antibody Allocation (excel) - Guidance Documents (ca.gov) – under the "Other" section – updated weekly

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37

Adverse Event Mandatory Reporting

- Clinical trials evaluating the safety of these mAbs are ongoing
- Completion of **FDA MedWatch Form** to report all medication errors and serious adverse events occurring during use of bamlanivimab and considered to be potentially related to bamlanivimab is mandatory and must be done by the prescribing healthcare provider and/or the provider's designee. These adverse events **must be reported within 7 calendar days from the onset of the event**
- Serious Adverse Events are defined as:
  - death;
  - a life-threatening adverse event;
  - inpatient hospitalization or prolongation of existing hospitalization;
  - a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
  - a congenital anomaly/birth defect;
  - a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

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38

Readiness Checklist: Administration of Outpatient mAbs under EUA

Allocate **dedicated space** and develop plan to **manage patient flow**
- ❑ Clear process for patients that are coming to clinical site including scheduling requirements
- ❑ Admission process for COVID-19 positive patients designed to minimize risk of spread per facility requirements / directions / guidelines'
- ❑ Dedicated room available for treatment

Ensure **dedicated source of supplies;** which may be difficult to procure
- ❑ Needed infusion components obtained
  - ❑ Example: IV kits, infusion chair, IV pole, vital sign monitoring equipment, emergency medications

Assign **sufficient personnel** to meet expected demand
- ❑ Sufficient staffing plans in place for Nurse/IV tech, Physician, Pharmacist
  - Likely need dedicated team to treat patients

Prepare for **drug administration** process
- ❑ Pre–visit: Clear treatment and monitoring plan developed for during infusion
- ❑ Treatment: 1-hour treatment and up 1-hour post-treatment observation
  - ❑ Emergency protocol defined for addressing potential infusion reactions or complications
- ❑ Post-treatment: Clear process for patient follow-up defined using telemedicine as possible

Ensure **process for reimbursement** in place (non-drug administrative costs)

Prepare for **reporting needs** for adverse events and record keeping

39

Unique challenges to bamlanivimab administration

40

Resources (1)

California SARS-CoV-2 Crisis Care Guidelines.

COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/.

COVID-19 Treatment Guidelines Panel. Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19. Available at https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-10.

California Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19

MedWatch
- Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
- Use a postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and returning by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA- 0178), or
- Call 1-800-FDA-1088 to request a reporting form

Operation Warp Speed Monoclonal Antibody Playbook:
https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Documents/OWS_MAB_%20playbook_10Nov20-508.pdf

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41

Resources (2)

California Monoclonal Antibody Allocation (excel) - Guidance Documents (ca.gov) - under the "Other" section – updated weekly

MHOAC Contact Information: https://emsa.ca.gov/medical-health-operational-area-coordinator/

Bamlanivimab
- Bamlanivimab EUA Letter of Authorization. U.S. Food and Drug Administration. Available at https://www.fda.gov/media/143602/download.
- Frequently asked Questions on the Emergency Use Authorization for Bamlanivimab. U.S. Food and Drug Administration. Available at https://www.fda.gov/media/143605/download.
- Fact Sheet for Health Care Providers Emergency use Authorization (EUA) of Bamlanivimab. U.S. Food and Drug Administration.
- Eli Lilly video for bamlanivimab preparation/administration: https://www.kaltura.com/index.php/extwidget/preview/partner_id/1750891/uiconf_id/30232671/entry_id/1_i3nkya7k/embed/dynamic?
  - Complete video transcript and more info: https://www.covid19.lilly.com/bamlanivimab/hcp/dosing-administration#dosing-and-administration

Casirivimab / Imdevimab
- Casirivimab / Imdevimab EUA Letter of Authorization. U.S. Food and Drug Administration. Available at https://www.fda.gov/media/143891/download.
- Frequently asked Questions on the Emergency Use Authorization for Casirivimab + Imdevimab. Available at https://www.fda.gov/media/143894/download.
- Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Casirivimab and Emdevimab (fda.gov).

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42

Thank you

Questions????

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- John Redd (ASPR)
- Kim McCoy Wade (CDA)
- Karen Mark (DHCS)

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43

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44

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45