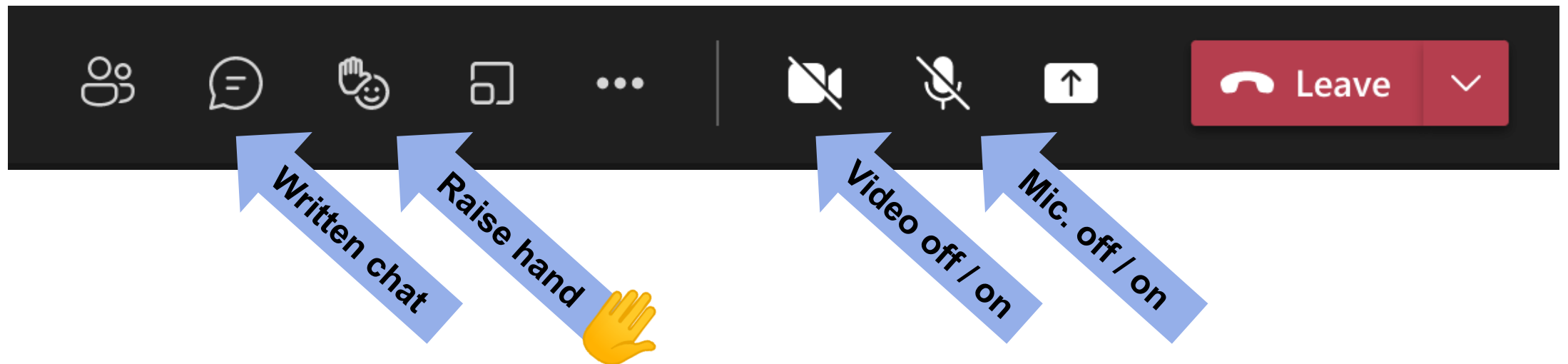# Welcome to the

California Department of Public Health

Special Session:
Therapeutic Treatments

Wednesday, January 26, 2022
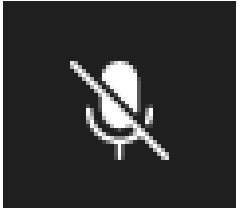
Vaccinate ALL 58

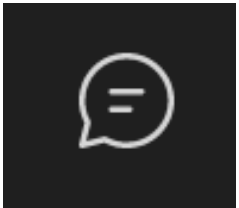Together we can end the pandemic.

Navigating the Teams Taskbar

Written chat

Raise hand

Video off / on

Mic. off / on

Leave

Use the chat or raise your hand to signal the host.

Turn video and microphone off and on to be seen and heard.

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Housekeeping

Reminder! Please mute yourself when not speaking to avoid feedback and background noise.

Please introduce yourself by adding your name, role and organization into the chat.

This session is being recorded. Slides and recording will be available on https://eziz.org/covid/education/

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Agenda: Wednesday, January 26, 2022

No.	Item	Speaker	Time (AM)
1	Welcome and Announcement	Leslie Amani (Moderator)	9:00 – 9:05
2	Gratitude and Overview	Tricia Blocher (CDPH)	9:05 – 9:10
3	SARS-COV-2 Outpatient Treatment and Prophylaxis	John Openshaw, M.D. (CDPH)	9:10 – 9:20
4	Health Partner Ordering Portal	Caroline Barnhill (CDPH)	9:20 – 9:30
5	Transfer and Redistribution	Alan Hendrickson (CDPH)	9:30 – 9:35
6	Resources and Referrals	Kate McHugh (CDPH)	9:35 – 9:40
	Q&A and Discussion		9:40 – 9:55
7	Wrap-up	Leslie Amani (Moderator)	9:55 – 10:00

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Announcement

Leslie Amani, CDPH

Therapeutics on EZIZ

NEW

CDPH COVID-19 Treatments now on EZIZ.

Link to CDPH Treatments webpage here

Gratitude and Overview

Tricia Blocher, CDPH Deputy Director

Gratitude and Overview

SARS-COV-2 Outpatient Treatment and Prophylaxis

John Openshaw, M.D., CDPH

Available Outpatient Therapies at Each Disease Stage

SARS-CoV-2 Negative (-)		SARS-CoV-2 Positive (+)
Prophylaxis		**Treatment**
Not Exposed	Exposed	Mild Illness or Moderate Illness
Long-Acting Monoclonal Antibody ➤ Tixagevimab /cilgavimab (EVUSHELD)	**Monoclonal Antibodies** ➤ Bamlanivimab/ etesevimab 🚫 ➤ Casirivimab/ imdevimab (REGEN-COV) 🚫	**Monoclonal Antibodies** ➤ Bamlanivimab/etesevimab 🚫 ➤ Casirivimab/imdevimab (REGEN-COV) 🚫 ➤ Sotrovimab **Antivirals** ➤ Nirmatrelvir/ritonavir (PAXLOVID) ➤ Molnupiravir (LAGEVRIO) ➤ Remdesivir (VEKLURY)

Treatment Options

🚫 Not effective against Omicron; as of January 24, **not** authorized for use in any USA state

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10

Currently Available Anti-SARS-COV-2 Treatments: Monoclonal Antibodies

Drug	Route	Age groups authorized for treatment	Timing of Treatment	Treatment Effectiveness	Activity Against Variants Currently Circulating
Sotrovimab 500 mg given as a single infusion	Intravenous	12 years and older and weighing at least 40 kg	As soon as possible, but within 10 days of symptom onset	Compared to placebo, 85% relative risk reduction in hospitalizations or deaths.	Effective against Delta and Omicron

Currently Available Anti-SARS-COV-2 Treatments: Antivirals

Drug	Route	Age groups authorized for treatment	Timing of Treatment	Effectiveness	Activity Against Variants Currently Circulating
Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid) Orally twice daily for 5 days	Oral	12 years and older and weighing at least 40 kg	As soon as possible, but within 5 days of symptom onset	Compared to placebo, a relative risk reduction of 89% in hospitalizations or deaths.	Effective against Delta and Omicron
Remdesivir (Veklury) 200 mg IV on Day 1, followed by 100 mg IV daily on Days 2 and 3	Intravenous	FDA approved in 12 years and older and weighing at least 40 kg; EUA for <12 years of age weighing 3.5 to 40 kg	As soon as possible, but within 7 days of symptom onset	Compared to placebo, a relative risk reduction of 87% in hospitalizations or deaths.	Effective against Delta and Omicron
Molnupiravir (Legevrio) 800 mg Orally twice daily for 5 days	Oral	18 years and older	As soon as possible, but within 5 days of symptom onset	Compared to placebo, a relative risk reduction of 30% in hospitalizations or deaths.	Effective against Delta and Omicron

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Prioritization of Treatment Options for Omicron

In order of preference, the NIH recommends using one of the following treatment options (considering a patient's full clinical status, including drug-drug interactions) for mild to moderate infection:

1. **Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid)** orally twice daily for 5 days, initiated as soon as possible and within 5 days of symptom onset in those aged ≥12 years and weighing ≥40 kg

2. **Sotrovimab 500 mg** as a single IV infusion, administered as soon as possible and within 10 days of symptom onset in those aged ≥12 years and weighing ≥40 kg who live in areas with a high prevalence of the Omicron VOC

3. **Remdesivir 200 mg** IV on Day 1, followed by **Remdesivir 100 mg** IV daily on Days 2 and 3, initiated as soon as possible and within 7 days of symptom onset in those aged ≥12 years and weighing ≥40 kg; EUA in children under the age of 12 years. Doses should be adjusted for pediatric patients.

4. **Molnupiravir 800 mg** orally twice daily for 5 days, initiated as soon as possible and within 5 days of symptom onset in those aged ≥18 years **ONLY** when none of the above options can be used.

Post-Exposure Prophylaxis

- Currently we have no FDA authorized or approved therapeutics for post-exposure prophylaxis

- Bam/Ete and REGEN COV are the only drugs with EUAs for post-exposure prophylaxis and neither are effective against Omicron

- As of January 24, 2022:

  - The FDA has revised bam/ete and REGEN COV EUAs to limit use to patients who are likely to have been exposed or infected to a variant that is susceptible to these treatments

  - Use of bam/ete and REGEN COV are **not authorized** for use in any US state

Anti-SARS-COV-2 Monoclonal Antibody for Pre-Exposure Prophylaxis

Drug	Route	Age groups authorized for treatment	Pre-Exposure Prophylaxis Effectiveness	Activity Against Variants Currently Circulating
Tixagevimab 150 mg / cilgavimab 150 mg (Evusheld) Given as two separate consecutive injections	Intramuscular	12 years and older and weighing at least 40 kg	Reduced the risk of developing symptomatic COVID-19 by 77% compared to placebo.	Effective against Delta and Omicron

AstraZeneca Storm Chaser Post-exposure Trial Update 6.15.21
AstraZeneca Provent Phase III Prophylaxis Trial 8.20.21
AstraZeneca Tackle Phase III Outpatient Treatment Trial 10.11.21
FDA: Fact Sheet EUA Evusheld

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Operationalizing

Mild to moderately ill outpatient with positive direct viral test

↓

Evaluate if candidate for outpatient therapy

↓

Select treatment option

See NIH Treatment Guidelines for:
- Guidance regarding patient eligibility
- Prioritization of patients for treatment when supplies are limited
- Prioritization of therapeutic options

Use of oral option

↓

Healthcare provider identifies dispensing location that has received shipment of Paxlovid or molnupiravir

↓

Communicate with dispensing location to ensure stock available

↓

Send prescription to dispensing location

To find dispensing locations, see:
- HHS Therapeutics Locator with map of locations with quantities in stock (based on daily reporting, not a guarantee of availability)

Use of IV option

↓

Identify infusion center if healthcare provider's facility does not have product

- Use HHS Treatment Locator for infusion centers to find locations

Regardless of treatment medication or route, patients should be reminded not to delay initiating treatment!

NIH Treatment Guidelines Statement on Therapies 1.19.22
HHS Therapeutics Locator: Orals & Evusheld
HHS Therapeutics Distribution

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16

California Allocations

Chart: Patient Courses (y-axis, 0 to 70000) by allocation date (x-axis: Sept 13, Sept 21, Sept 27, Oct 4, Oct 11, Oct 18, Oct 25, Nov 1, Nov 8, Nov 15, Nov 29, Dec 13, Dec 17, Dec 27, Jan 3, Jan 10, Jan 17, Jan 24)

Legend: Bam/Ete, REGEN COV, Sotrovimab, Paxlovid, Molnupiravir
Active against Omicron

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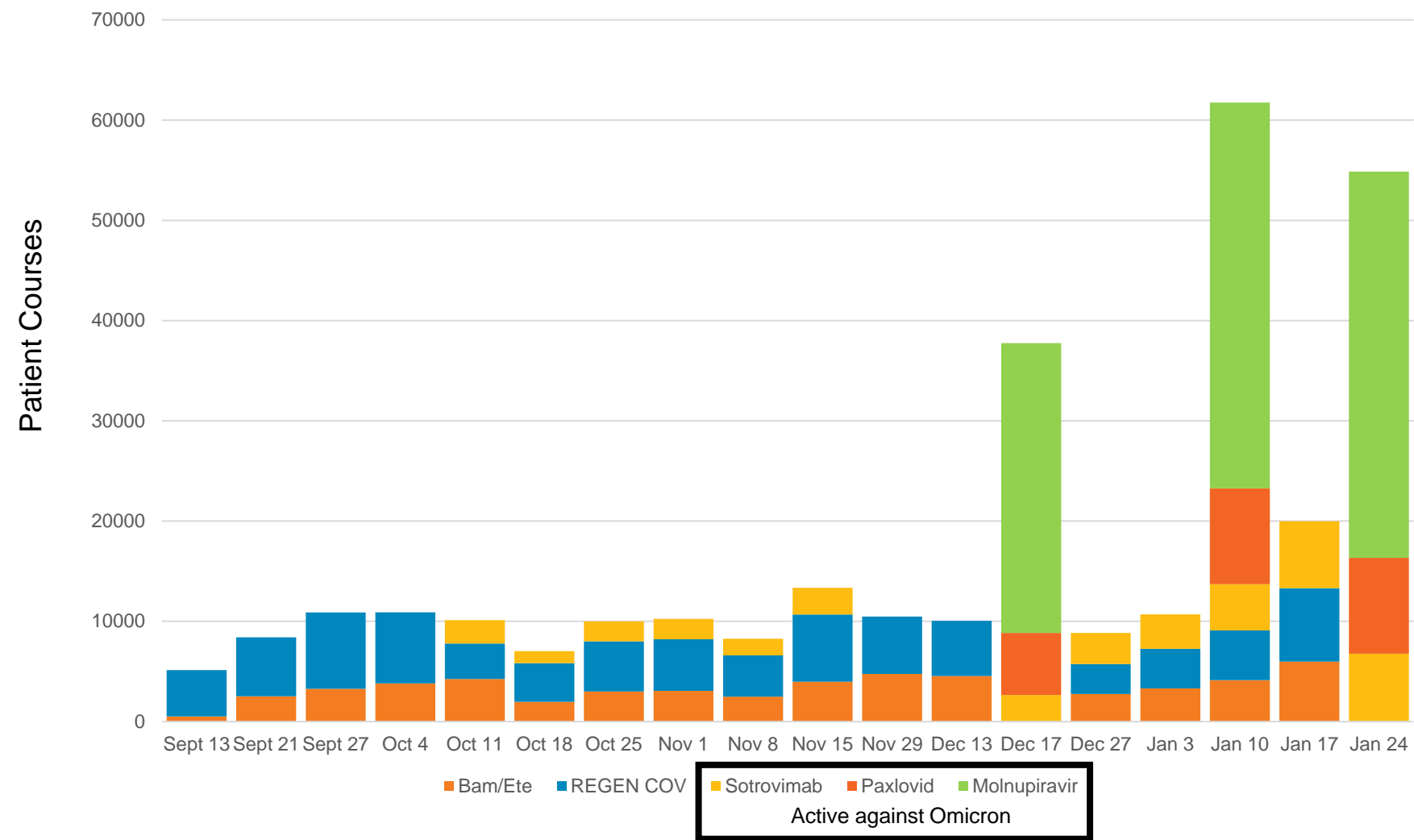
Allocation for Products Active Against Omicron

Product and Route	Authorized Indication	Distribution Point	Allocation
Sotrovimab IV anti-SARS-CoV-2 monoclonal antibody	Treatment of mild to moderately ill outpatients with positive SARS-CoV-2 viral test	Facilities able to provide infusion services and monitor patients; number of courses for each site determined by Medical Health Operational Area Coordinators at county level	Allocated to counties Based on new cases (7-day average) and new COVID-19 hospitalizations (7-day average). Weighted 75% to cases; 25% to hospitalizations.
Paxlovid Oral protease inhibitor **Molnupiravir** Oral nucleoside analogue	Treatment of mild to moderately ill outpatients with positive SARS-CoV-2 viral test	Allocated to a limited number of pharmacies that can dispense in each county, final list determined by local jurisdictions	Allocated to counties Based on new COVID-19 cases (7-day average) and Healthy Places Index (HPI); with 50% weighted to cases and 50% weighted to HPI. Within the 50% allocated by HPI, 40% to Q1 (most disadvantaged); 30% to Q2; 20% to Q3; 10% to Q4.
Evusheld IM anti-SARS-CoV-2 monoclonal antibody	Pre-exposure prophylaxis	Distributed to mutual aid regions (6 regions), with instructions to send courses to transplant and cancer centers	Allocated to mutual aid regions Within each region, allocation based on share of the population in different equity quartiles; 40% of state allocation to Q1; 30% to Q2; 20% to Q3; 10% to Q4.

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CDPH COVID-19 Treatments Webpage

NEW

- FAQs for general public and healthcare providers

- Information on allocation, distribution, and ordering

- Drug fact sheets

- Links to further resources

- Linked in the "Protect Your Health" section on the CDPH COVID-19 webpage
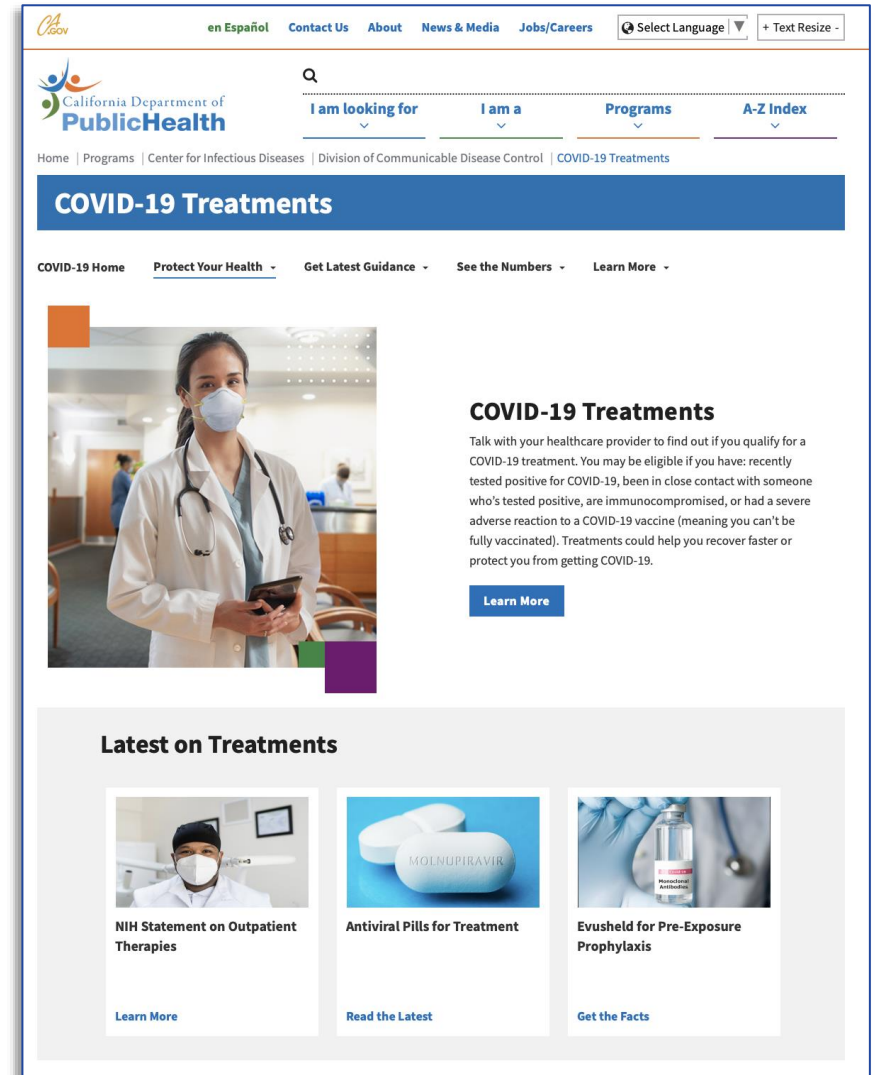
Health and Human Services Therapeutics Locator

COVID-19 Therapeutics Locator

The national map below displays public locations that have received shipments of U.S. Government-procured COVID-19 therapeutics under U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) authority. The locations displayed in the locator have reported stock on hand within the last day.

The monoclonal antibody treatment Evusheld (Astra Zeneca), as well as the oral antiviral therapies Paxlovid (Pfizer), and molnupiravir (Merck) are products authorized by the FDA for either prevention (Evusheld) or treatment (Paxlovid and molnupiravir) of COVID-19.

These therapies

This therapeutics locator is intended for provider use, as the included therapies require a prescription by a licensed and authorized provider. Patients should not contact locations directly.

Therapeutic Distribution Locator for Provider Use

State, Territory, or Jurisdiction
California

Therapeutic Selector
All

Locations
747

60 MDSS/SGSLM
101 BODIN CIRCLE, Travis AFB, CA 94535
Paxlovid, Product #0069-1085-30
/20 (Available/Allotted)

60 MDSS/SGSLM
101 BODIN CIRCLE, Travis AFB, CA 94535
Molnupiravir, Product #0006-5055-06
/20 (Available/Allotted)

9th Med Grp
15301 Warren Shingle Rd, Beale AFB, CA 95903
Molnupiravir, Product #0006-5055-06
/40 (Available/Allotted)

9th Med Grp
15301 Warren Shingle Rd, Beale AFB, CA 95903
Paxlovid, Product #0069-1085-30
/20 (Available/Allotted)

ADVENTIST HEALTH HANFORD
115 Mall Drive, Hanford, CA 93230
Molnupiravir, Product #0006-5055-06
/80 (Available/Allotted)

ADVENTIST HEALTH ST HELENA HOSPITAL
10 Woodland Rd., St Helena, CA 94574
Evusheld, Product #0310-7442-02
24/48 (Available/Allotted)

ADVENTIST HEALTH ST HELENA HOSPITAL
10 Woodland Rd., St Helena, CA 94574
Paxlovid, Product #0069-1085-30
/20 (Available/Allotted)

Use search glass below to find locations near an address.

Zoom to   Pan   1 of 5

Rite Aid 06295
1101 FRESNO STREET, FRESNO, CA 93706-3235

Therapeutic: Paxlovid
Courses Available: 19
Total Courses Allotted: 80
Last Order Date: 01/13/2022 12:00:00 AM
Last Date Delivered: 12/30/2021 12:00:00 AM

Available Evusheld Courses
14,661
Total Allotted: 23,736

Available Molnupiravir Courses
45,084
Total Allotted: 63,580

Available Paxlovid Courses
6,826
Total Allotted: 15,840

NIH Treatment Guidelines Statement on Therapies 1.19.22
HHS Therapeutics Locator: Orals & Evusheld
HHS Therapeutics Distribution

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Health Partner Ordering Portal

Caroline Barnhill, CDPH

Health Partner Ordering Portal (HPoP) Weekly Allocations

- Three therapeutics are processed through HPoP:
  - Evusheld
  - Paxlovid
  - Molnupiravir
- Allocation numbers are released Monday to the counties/regions.
- Specific site allocations are coordinated through the locals and region and are based on those previously identified and entered into HPoP and the ordering spreadsheet.
- New sites cannot be added at this time unless coordinated through and approved by, the county/region. These site additions can only be accepted when submitted by the county/region.
- Providers cannot place orders themselves at this time. Orders are entered by the State.

HPoP – Activating Accounts

- Once approved, a site will be entered into HPoP. Providers should expect to receive an email to activate their account.

  ○ Please note, this will NOT occur immediately. It will take 24 to 48 hours from the time the state receives the information, NOT when the information is given to the counties.

- If providers do not receive an email and was/is a vaccine provider, they should try using their vaccine login on this site: CDC VPoP Provider Sign-in Page

  ○ HPoP is different than Vaccine Partner Ordering Portal (VPoP). Logging into VPoP will not show therapeutics accounts.

- Any issues with accessing accounts can be sent to cdphtherapeutics@cdph.ca.gov.

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HPoP – Verifying Accounts

- Accounts must be verified by the contacts associated with the site account. No orders can be placed without this step.

- What does verifying an account mean?

  - One contact listed on the account must log in, ensure the site address is correct/make any changes, and enter open hours.

  - Once reviewed and hours entered, the contact will need to click the "address and hours verified" check box at the bottom and then "apply changes."

  - A banner at the top of the account will show "therapeutic address verified."

  - If the banner says, "therapeutic address needs verification," the site is not yet fully activated and is not eligible for orders.
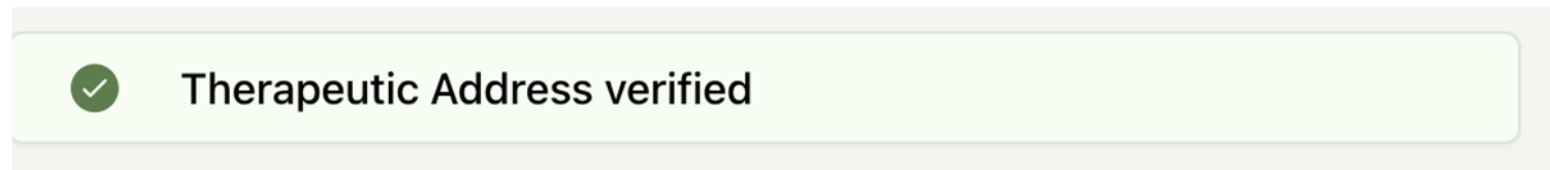
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HPoP – Verifying Accounts (continued)

- Account verification not completed

⚠ Therapeutic Address needs verification
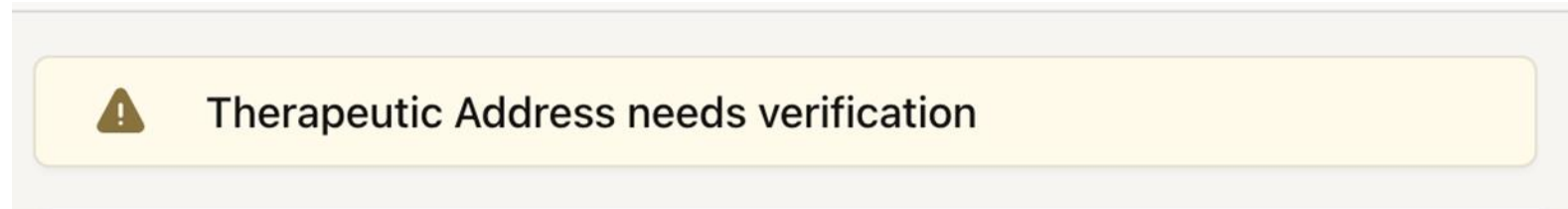
- Account verification completed

✓ Therapeutic Address verified

HPoP – How to Verify an Account

Provider Details   **Receiving Address / Hours**   Permissions

Receiving Address / Hours   ⊞

✎ Physical   **3104 PONTE MORINO DR STE 110**
CAMERON PARK EL DORADO CA 95682   T

HPoP – How to Verify an Account (continued)

HPoP – Ordering and Shipping Status

- Can be viewed in the site account under "Therapeutic Orders"
- If the status shows anything other than "canceled," it is active and in process.
  - There is nothing else the provider needs to do.
- Orders can take 4-7 business days to arrive once the order is entered into HPoP by the State.
- Shipping can be tracked in HPoP or via Third-party Redistributor (TPR, AmerisourceBergen) Sign-in
  - If the order does not appear in the TPR Amerisource shipping site, it has not yet shipped.

HPoP – Reporting Inventory

- Must be entered daily.
- Not cumulative, e.g.:
  - Day one entry: 5 of 20 administered
  - Day two entry: 5 of 15 administered

Transfer and Redistribution

Alan Hendrickson, CDPH

Transfer and Redistribution of Therapeutics

Transfer and Redistribution of Therapeutics

Why "No!":

- Consistency giving the low allocation of all therapeutics
- HPoP does not support redistribution
  - Inventory/Usage reporting remains the responsibility of the redistributor
  - Inventory may impact future allocations
- HPoP does support the transfer of therapeutics but:
  - Therapeutics are allocated by Operational Area (county) and mutual aid region
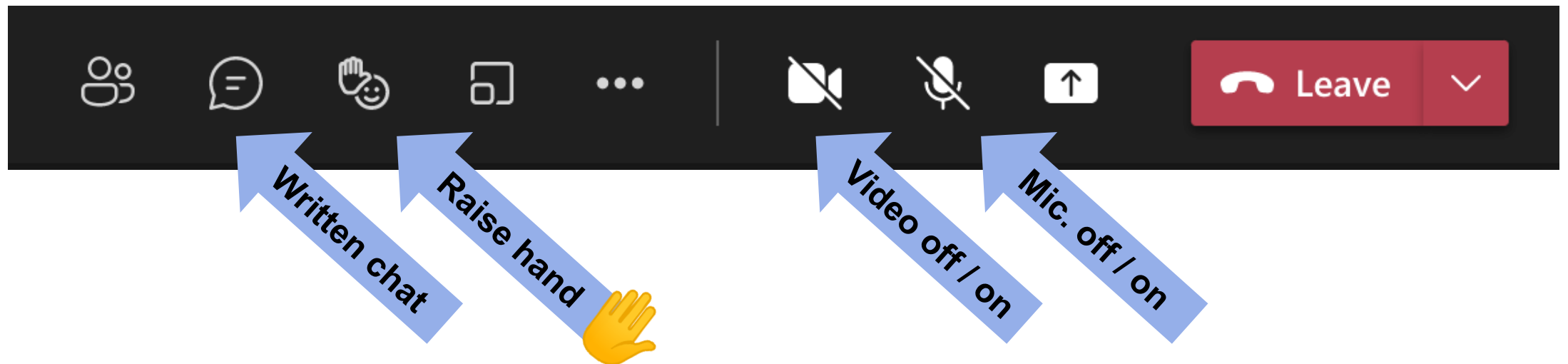 - Redistribution & transfers may adversely impact allocation

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Resources

Kate McHugh, CDPH

Resources

- CDPH Therapeutics: cdphtherapeutics@cdph.ca.gov
- CDPH COVID-19 Therapeutics Webpage: CDPH COVID-19 Treatments Webpage
- Weekly Update Email
- Third-party Redistributor (TPR, AmerisourceBergen) - Track My Shipment Website: AmerisourceBergen Link: Track My Shipment
- Reimbursement for Antivirals and Monoclonal Antibodies
  - Reimbursement of antivirals: CMS Oral Antiviral Guidance

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Resources (continued)

- Reimbursement for Antivirals and Monoclonal Antibodies

  - Reimbursement of antivirals: CMS Oral Antiviral Guidance

  - Reimbursement of monoclonal antibodies: Reimbursement of COVID-19 Vaccine and Monoclonal Antibody Administration for Medical Providers

  - Medicare coding and billing for monoclonal antibody infusions: Monoclonal Antibody COVID-19 Infusion | CMS.

  ○ For additional information please email CDPH at cdphtherapeutics@cdph.ca.gov

- Purchasing Remdesivir: c19therapies@amerisourcebergen.com

FDA Statement: Monoclonal Antibodies_1.24.22

Navigating the Teams Taskbar

Written chat

Raise hand

Video off / on

Mic. off / on

Use the chat or raise your hand to signal the host.

Turn video and microphone off and on to be seen and heard.

Wrap-up

Leslie Amani, CDPH

Thank you for your commitment to protect the health and well-being of all Californians!

Thank you for joining today's webinar!