Talking with Patients about COVID-19 Therapeutics

Thursday, February 23, 2023
Continuing Medical Education Disclosure

All planners, staff, and others involved with this activity have reported no relevant financial relationships with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

This activity has not received commercial support.

Dr. Alex McDonald’s children
Questions

During today's session, please use the Q&A panel to ask your questions so CDPH subject matter experts can respond directly.

Helpful resource links will be dropped into the “chat.”
Housekeeping

For Attendees: This session is being recorded. Please access today’s slides and recording through the following link: EZIZ COVID Crucial Conversations

Please use “Q&A” to ask questions.

For post-webinar questions, contact rachel.jacobs@cdph.ca.gov
<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Speaker</th>
<th>Time (PM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Welcome</td>
<td>Rachel Jacobs (CDPH)</td>
<td>12:00 – 12:05</td>
</tr>
<tr>
<td>2</td>
<td>Talking with Patients about COVID-19 Therapeutics</td>
<td>Alex McDonald, MD, FAAFP, CAQSM</td>
<td>12:05 – 12:40</td>
</tr>
<tr>
<td>3</td>
<td>Q&amp;A and Resources</td>
<td>Rachel Jacobs (CDPH)</td>
<td>12:40 – 1:00</td>
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</tbody>
</table>

**Agenda: Thursday, February 23, 2023**
Poll: CDPH appreciates your feedback!

How confident are you in your ability to effectively talk with patients about COVID-19 therapeutics?

- Very confident
- Confident
- Somewhat confident
- Slightly confident
- Not confident
Talking with Patients about COVID-19 Therapeutics

Alex McDonald, MD, FAAFP, CAQSM
Co-Founder of #ThisIsOurShot and #VacunateYa
Goals & Objectives

Participants will learn:
1. Current state of COVID-19
2. COVID-19 prevention
3. COVID-19 outpatient treatment
4. How to talk with patients about COVID-19 therapeutics
Weekly Trends in Number of COVID-19 Cases
United States Data, CDC

Likely Underreporting
AN OUNCE OF PREVENTION IS WORTH A POUND IN CURE

Benjamin Franklin

COVID-19 vaccination is our best tool in preventing COVID!
COVID-19 Vaccine Effectiveness

Death Rates by Vaccination Status and Receipt of 1st and 2nd Booster Doses Among People Ages 50+ Years
April 3–July 2, 2022 (25 U.S. Jurisdictions)

In June 2022, people ages 50 years and older with ≥2 booster doses had 14 times lower risk of dying from COVID-19, compared to unvaccinated people and 3 times lower risk of dying from COVID-19 than people with one booster dose.
CDC adds COVID vaccine to routine immunization schedule for kids, adults

MMWR: ACIP Immunization Schedules for Children & Adolescents
MMWR: ACIP Immunization Schedule for Adults
CDC Immunization Schedule Pages
Disparities in COVID-19 Treatments: HPI Quartiles

This chart uses the **Healthy Places Index 3.0 (HPI)**, developed by the Public Health Alliance of Southern California. The HPI uses a range of data sources and indicators to calculate a measure of community conditions ranging from the most to the least healthy based on economic, housing, and environmental measures. Scores range from **less healthy community conditions in Quartile 1** to **more healthy community conditions in Quartile 4**.

Source: CDPH Therapeutics Allocation Dataset
Racial and Ethnic Disparities in COVID-19 Treatment

During April–July 2022, the percentage of COVID-19 patients ages 20 years and older treated with Paxlovid was 36% and 30% lower among Black and Hispanic patients than among White and non-Hispanic patients, respectively.
Age Disparity in COVID-19 Deaths Worsened

Sources: CalRedie, CAIR vaccine registry, covid19.ca.gov
Share of Skilled Nursing Facility (SNF) Cases Treated with Therapeutics and Case Counts
California, 2022-2023
Testing. Testing. Testing!

• Early testing and treatment is key
• Many treatment options require initiation in the first 5 days
• When in doubt, test!
• Based on FDA EUA, a positive test is not required for Paxlovid Rx, only a current diagnosis (which can be based on exposure and symptoms)
• Testing is widely available
  o May change after end of pandemic declaration May 11
• Note: Lack of testing should not be a barrier to prescribing therapeutics
Outpatient treatment (preferred)

- Early treatment has shown to reduce progression to severe illness or hospitalization
- **Nirmatrelvir with ritonavir (Paxlovid)** – PO bid x5 days
- **Remdesivir (Veklury)** - IV daily x 3 days
Outpatient treatment (not preferred)

- **Molnupiravir** - PO bid x 5 days (only if Paxlovid not available)

- **Monoclonal Antibodies** - recommends **against** use because the dominant Omicron subvariants in the United States are not expected to be susceptible to these products
Patients at High Risk of Severe COVID-19

- Age >50
- Asthma
- Cancer
- CKD
- CVA
- Chronic Lung Disease
  - COPD, PAH, Bronchiectasis
- Chronic Liver Disease
- Diabetes
- Obesity BMI >30
- Chronic Mental Health
  - Bipolar, Schizophrenia
- Pregnancy
- Physical Inactivity
- Immunocompromised
- Smoker
- Cardiac – CAD/CHF
Nirmatrelvir with Ritonavir (Paxlovid)

- Nirmatrelvir oral protease inhibitor that is active against $M^{\text{PRO}}$, a viral protease that plays an essential role in viral replication
- Ritonavir a strong cytochrome P450 (CYP) 3A4 inhibitor and pharmacokinetic boosting agent that has been used to boost HIV protease inhibitors
- Coadministration of ritonavir is required to increase nirmatrelvir concentrations to the target therapeutic range
- Treatment initiated within 5 days of symptoms onset
- **Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid)** orally (PO) twice daily for 5 days in nonhospitalized patients aged $\geq 12$ years
## Effectiveness of Paxlovid in Reducing Severe Coronavirus Disease 2019 and Mortality in High-Risk Patients

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Paxlovid No.</th>
<th>Non-Paxlovid No.</th>
<th>Hazard Ratio (95% CI)</th>
<th>Interaction P Value</th>
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<tbody>
<tr>
<td>Overall</td>
<td>4737</td>
<td>175,614</td>
<td>0.54 (.29, .75)</td>
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<tr>
<td>Adequate COVID-19 vaccination</td>
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<td>No</td>
<td>1051</td>
<td>43,818</td>
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<td>3686</td>
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<td>Age category</td>
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<td>&lt;60 years</td>
<td>973</td>
<td>102,040</td>
<td>1.06 (.36, 3.15)</td>
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<tr>
<td>≥60 years</td>
<td>3784</td>
<td>73,574</td>
<td>0.92 (.38, .73)</td>
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<tr>
<td>Sex</td>
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<tr>
<td>Males</td>
<td>1992</td>
<td>71,957</td>
<td>0.60 (.40, .82)</td>
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<tr>
<td>Female</td>
<td>2745</td>
<td>103,647</td>
<td>0.66 (.46, .88)</td>
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<td>Population sector</td>
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<tr>
<td>All</td>
<td>300</td>
<td>32,750</td>
<td>0.75 (.32, 1.77)</td>
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<td>Ultra-Orthodox Jewish</td>
<td>202</td>
<td>6,655</td>
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<td>General Jewish</td>
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<td>Socioeconomic status</td>
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<td>Low</td>
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<td>6,618</td>
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<td>Middle</td>
<td>2090</td>
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<td>406</td>
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<td>Chronic kidney disease</td>
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<tr>
<td>No</td>
<td>4509</td>
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<td>Yes</td>
<td>231</td>
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<td>Neurological disease</td>
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<td>Yes</td>
<td>327</td>
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<td>Malignancy in the prior year</td>
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<td>Yes</td>
<td>178</td>
<td>15,201</td>
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<td>Immunosuppression</td>
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<td>.042</td>
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<td>Yes</td>
<td>316</td>
<td>1,214</td>
<td>0.26 (.13, .48)</td>
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</table>

Nirmatrelvir with ritonavir (Paxlovid)
Nirmatrelvir with Ritonavir (Paxlovid)

- Drug-drug interactions
  - Ritonavir component CYP-450 inhibition
  - COVID-19 Drug Interactions website

- Viral Rebound
  - Rebound symptoms can also occur in the absence of treatment
  - Rebound not associate with progression to severe illness

- Chronic Kidney Disease
  - Dose reduce to nirmatrelvir 150 mg - ritonavir 100 mg twice daily in patients with GFR ≥30 to <60 mL/min

- Other
  - Taste alterations “cherry motor oil”, diarrhea, hypertension, and myalgia
  - Mint or gum may be helpful
Remdesivir

- Nucleotide Prodrug – binds to the viral RNA-dependent RNA polymerase and inhibits viral replication by terminating RNA transcription prematurely
- Intravenous remdesivir patients aged ≥28 days
- IV 200 mg as a single dose on day 1, followed by 100 mg once daily.
- Non-hospitalized patients should be started within 7 days of symptom onset - administered for 3 days
- Hospitalized patients should be started within 7 days of symptom onset - administered for 5 days or until discharge
Remdesivir plus standard of care versus standard of care alone for the treatment of patients admitted to hospital with COVID-19 (DisCoVeRy): a phase 3, randomized, controlled, open-label trial.
Remdesivir Shortens Time to Recovery

NEJM: Remdesivir for the Treatment of COVID-19
3 consecutive days of IV RDV resulted in an 87% relative reduction in the risk of hospitalization or death when compared to placebo.

Remdesivir

• Side Effects
  o Nausea, elevated transaminase levels, an increase in PTT, anaphylaxis

• Baseline Labs
  o GFR, liver function, and prothrombin time tests
  o Discontinued if ALT increases to >10 times the upper limit of normal

• Chronic Kidney Disease
  o Not to be used in patients with GFR ≤ 30 mL/min

• Pregnancy
  o Not included in clinical trial, but good real-world data is reassuring
Molnupiravir

- Prodrug of beta-D-N4-hydroxycytidine (NHC)
- NHC uptake by viral RNA-dependent RNA-polymerases results in viral mutations and lethal mutagenesis
- Only when Paxlovid is not available
- Must use contraception before and after treatment (regardless of gender), not recommended in pregnancy
- Treatment initiated within 5 days of symptoms onset
- molnupiravir 800 mg orally (PO) twice daily for 5 days
Molnupiravir reduced the rate of hospitalization or death among patients by 31% compared to placebo.
Molnupiravir

- Not preferred agent
- Diarrhea, nausea, and dizziness
- Cannot use in Pregnancy
  - Contraception 4 days after completing course (all genders)
- Adults >18
- Chronic Kidney Disease
  - No dosing adjustment
Before Prescribing

• Renal function and liver tests are **not required**
• Asking a patient re liver or kidney health is enough
• But use your best clinical judgment
• Standing Paxlovid orders with RN assessment are acceptable
How to Talk with Patients about COVID-19
Therapeutics
“I’m not that sick.”

- COVID-19 treatment needs to be started within 5 or 7 days of symptom onset. If you wait until symptoms worsen, it may be too late.
- Mild symptoms can progress to severe.
- Treatment can significantly reduce your risk of severe illness, hospitalization and may reduce risk of long COVID.
"I’m not high risk."

• Most adults are at risk of serious complications from COVID-19
  o Obesity BMI >30
  o Physical Inactivity
  o Age >50 years
  o Unvaccinated
“Treatment has dangerous side effects”

- Always a concern, which is why discussion with a clinician is required
- Paxlovid study <10% had side effects
  - Bad taste (6%)
  - Diarrhea (3%)
- Drug-drug interactions need to be carefully assessed
“Medications cause COVID-19 rebound.”

• COVID-19 rebound can occur with or without treatment.

• Less than 20% of people experience COVID-19 rebound.
  o Rebound has been reported at higher rates in those who take Paxlovid.

• If symptoms do return, they are often mild.
Conversation Methodology: COVID-19 Therapeutics

To address patients concerns related to COVID-19 therapeutics, use the 3-5-3 method.

<table>
<thead>
<tr>
<th>3</th>
<th>5</th>
<th>3</th>
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</thead>
<tbody>
<tr>
<td>Steps to Start the Conversation</td>
<td>Key Messages</td>
<td>Steps to Wrap Up the Conversation</td>
</tr>
</tbody>
</table>

Therapeutics Myths and Facts
3 Steps to Initiating/Continuing Conversations

1. Ask and listen to the answer
   “What do you think about COVID-19 treatments?”
   “Why do you feel that way?”
   “What concerns do you have about the medications?”

2. Create an alignment of safety
   "I also want to weigh the risks and benefits. Let’s decide together what’s safest here.”
   “We both want what's safest for you, right now and into your future.”

3. Find common goals
   “We all want to be able to recover quickly without needing hospitalization.”
   “What reasons would motivate you to take treatments?”
   Find their personally motivating reason.
Key Messages

The treatments can keep you safe.

The medications will protect you from getting very sick and may prevent long COVID. Over one million Californians have safely taken Paxlovid.
Side effects are uncommon and usually mild.

Side effects happen in less than 1 out of every 10 people who take the medications. During treatment, some people temporarily have:

- Unpleasant taste in the mouth (mints can help)
- Diarrhea
- General malaise
Key Messages

3 Treatments are very effective.

Anti-viral medications are extremely effective at preventing hospitalization and death from COVID-19 and its variants.
Key Messages

Rebound is often misunderstood.

Viral rebound can happen with or without treatment and is usually mild. Most people do not get rebound.
Key Messages

I am glad you want to know more. Ultimately, the choice is yours. If you want more information, go to https://covid19.ca.gov/treatment/
3 Steps to Wrap Up the Conversation

1. Acknowledge their agency and personal choice
   “I want you to get treated today, but ultimately it’s your choice.”
   “I’m here as a resource to help you.”

2. Keep lines of communication open
   Trust is a journey. Give folks a way to reach you that you are comfortable with as they consider their decision.

3. Offer more information
   Offer COVID-19 Treatment Patient Education.
“Where Can I Learn More?”

- COVID-19 Therapeutics Warmline
  - 1-866-268-4322 (1-866-COVID-CA)
  - M-F, 6am – 5 pm PST

- COVID-19 Test to Treat Equity ECHO for support. To learn more about these sessions and to register, click here

- Frequently Asked Questions document for clinics, providers, and pharmacists

- The CCI/CDPH Test to Treat Resource Hub can be found here: https://www.careinnovations.org/covid-19-therapeutic-information/
Resources and Q&A
Rachel Jacobs, CDPH
During today's session, please use the Q&A panel to ask your questions so CDPH subject matter experts can respond directly.

If you have COVID-19 Therapeutics questions, post-webinar, please email rachel.jacobs@cdph.ca.gov
Poll: CDPH appreciates your feedback!

How confident are you in your ability to effectively talk with patients about COVID-19 therapeutics?

- Very confident
- Confident
- Somewhat confident
- Slightly confident
- Not confident
Therapeutics Myths and Facts

How to dispel misinformation about treatments

**MYTH:** I don’t need medication for a mild-to-moderate illness.

**PROVIDER ANSWER:** Most of us are used to walking out with a cold and flu symptoms to see if they get “bad enough” to need treatment. COVID-19 is different: lots of us are still at risk of having our mild or moderate syndromes develop into something more serious. The treatments used keep you out of the hospital and prevent you from dying, and early evidence shows they may even reduce your chance of developing long COVID.

**MYTH:** I’m not high risk.

**PROVIDER ANSWER:** Most of us think of ourselves as “low risk.” However, there are many factors that correlate even very healthy people not susceptible to becoming very ill from COVID-19. The truth is, the majority of adults fall into one of these categories. They include:

1. Advanced age
2. People living with diabetes, mental- or chronic diseases (arthritis, depression, ADHD), and mental chronic lung disease (including asthma), chronic kidney disease, and cardiovascular disease.
3. People who are overweight, physically inactive, or smoke.
4. People who are negatively affected by social determinants of health, such as race, ethnicity, socioeconomic status, or limited access to healthcare.
5. People who are unimmunized or not up-to-date with vaccinations.

Scan the QR code to read more about COVID-19 treatment resources.

January 2023  •  © 2023, California Department of Public Health
Join #ThisIsOurShot / #VacunateYa for newsletters about COVID-19 and vaccine-related talking points, and social media tips for physicians: https://thisisourshot.info/ / https://vacunateya.com/

Join Shots Heard Round the World to connect with a network of health professionals dedicated to combating online harassment of HCPs: https://shotsheard.org/

Health Defend is the evolution of these three programs. It is designed to educate, empower, equip, and defend healthcare professionals so they feel confident amplifying their trusted voice through social media. https://www.healthdefend.com/
# COVID-19 Therapeutics: Resources and Support

<table>
<thead>
<tr>
<th>Type of Support</th>
<th>Description</th>
<th>Updated 2.21.23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Guidance</td>
<td><strong>COVID-19 Therapeutics Warline</strong>: 1-866-268-4322 (866-COVID-CA) is a real time resource for all CA health care providers to access clinical consultation <strong>Monday through Friday 6 am – 5 pm</strong>. (Messages left after hours will be returned on the next business day.) You will be able to speak to a clinician or pharmacist from the UCSF National Clinician Consultation Center.</td>
<td></td>
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| General Information| **CDPH COVID-19 Treatments Webpage** (provides general information for healthcare providers, allocations, distribution and ordering, drug facts sheets, and additional resources)  
  - **CDPH COVID-19 Treatments Job Aid** (questions and answers for the public on COVID-19 therapeutics)  
  **COVID-19 Therapeutics Best Practices Checklist** (testing, prescribing, dispensing, and more)  
  Frequently Asked Questions document for clinics, providers, and pharmacists |                 |
| Locating Resources | Finding Providers and Test-to-Treat Sites  
  - **COVID-19 Therapeutics Locator** (arcgis.com) or call 1-800-232-0233 (TTY 888-720-7489)  
  - **Test-to-Treat** (hhs.gov) |                 |
| Questions          | For general CDPH Therapeutics questions, please email COVIDRxProviders@cdph.ca.gov  
  For ordering, program inquiries, signing up new HPoP Accounts: please e-mail CDPHTherapeutics@cdph.ca.gov |                 |
California Providers Stay Informed!
To be added to CDPH messaging services is as easy as 1-2-3!

1. **COVID-19 Vaccine** Provider Listserv Emails: Please email blanca.corona@cdph.ca.gov

2. **COVID Therapeutics:**

   **COVID Tx Providers Newsletter Sign Up**

   - First Name*
   - Last Name*
   - Email*
   - Organization/Clinic*
   - Role/Title*

   Sign up to the following newsletters:
   - ☑ COVID Tx Providers/LHJs

   [Submit]

   **COVID-19 Therapeutics Newsletter Sign-up**

3. **Mpox**

   **Mpox Newsletter Sign Up**

   - First Name*
   - Last Name*
   - Email*
   - Organization/Clinic*
   - Role/Title

   Sign up to the following newsletters:
   - ☑ Mpox-Providers, LHJ & Leadership

   [Submit]

   **Mpox Newsletter Sign-up**
Next Crucial Conversations Webinar: Talking with Patients about COVID-19 Misinformation

**Speaker:** Asha Shajahan, MD, MHSA  
**When:** Wednesday, March 8, 2023  
**Time:** 12:00PM-1:00PM  
[Register here!]
Upcoming Opportunities

**Monday**

*My Turn and myCAvax Office Hours*
Next session: Monday, March 6, 12PM

**Friday**

*Provider Consolidated Webinar*
Next session: Friday, February 24, 9AM-10:30AM
90 minutes to include
COVID-19 Vaccine and COVID-19 Therapeutics
Special Thanks to
Today's Presenter:
Alex McDonald, MD, CAQSM, FAAFP

Webinar Planning & Support:
Kenna Lee, Selena Polston, Tyler Janzen, Blanca Corona, Rachel Jacobs