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



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 <u>rachel.jacobs@cdph.ca.gov</u>

Agenda: Thursday, February 23, 2023

No.	ltem	Speaker	Time (PM)
1	Welcome	Rachel Jacobs (CDPH)	12:00 – 12:05
2	Talking with Patients about COVID-19 Therapeutics	Alex McDonald, MD, FAAFP, CAQSM	12:05 – 12:40
3	Q&A and Resources	Rachel Jacobs (CDPH)	12:40 – 1:00

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



AN OUNCE OF PREVENTION IS WORTHA DOUDD IN CURE Benjamin Franklin

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

COVID-19 Vaccine Effectiveness



CDC MMWR: COVID-19 and Mortality Among Unvaccinated and Vaccinated Persons Aged ≥12 Years by Receipt of Bivalent Booster Doses and <u>Time Since Vaccination</u> <u>CDC ACIP Slides: Bivalent COVID-</u>19 Vaccine Booster Doses HEALTHCARE

CDC adds COVID vaccine to routine immunization schedule for kids, adults

SHARE

TWEET

BY NATHANIEL WEIXEL - 02/09/23 6:06 PM ET

MMWR: ACIP Immunization Schedules for Children & Adolescents

MMWR: ACIP Immunization Schedule for Adults

CDC Immunization Schedule Pages



COVID-19 Therapeutics Data

Disparities in COVID-19 Treatments: HPI Quartiles



This chart uses the <u>Healthy Places Index 3.0 (HPI)</u>, 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**.

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
 - 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 <u>against</u> 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^{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 ≥12 years

Subgroup	Paxlovid No.	Non-Paxlovid No.	Hazard Ratio (95% Cl)				Interaction P Value
Overall	4737	175 614	0.54 (.39, .75)		_		
Adequate COVID-19 vaccination							.129
No	1051	43818	0.52 (.32, .82)				
Yes	3686	131796	0.62 (.39, .98)				
Age category	5000	101720	0.02 (100, 100)		-		.039
<60 years	973	102 040	1.06 (.36, 3.15)				
≥60 years	3764	73 574	0.52 (.36, .73)		_	-	
Sex	5704	13314	0.52 (.50, .75)		1 and 1		.514
Males	1992	71967	0.60 (.40, .91)		100 million (100 m		.514
Females	2745	103 647	0.46 (.26, .80)		and the second second		
Population sector	2/45	103 047	0.40 (.20, .00)				.708
Arab	300	32 758	0.75 (.32, 1.77)		100		.708
Ultra-Orthodox Jewish	202	6835					
			0.39 (.05, 2.89)	-			
General Jewish	4234	135 464	0.53 (.37, .76)				
Socioeconomic status	2022	010000000			22 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	30.00	.846
Low	1120	62 618	0.74 (.42, 1.29)				
Middle	2090	74 928	0.47 (.29, .75)				
High	1517	37 022	0.45 (.21, .97)			-	
Diabetes							.257
No	2911	139767	0.61 (.40, .93)			-	
Yes	1826	35 487	0.44 (.25, .75)				
Cardiovascular disease							.028
No	3231	152 121	0.64 (.41, 1.00)			-	
Yes	1506	23 493	0.43 (.26, .70)				
Chronic lung disease					1985		.114
No	4238	169 385	0.45 (.30, .67)				
Yes	499	6229	0.96 (.53, 1.73)			-	
Chronic kidney disease	100	0220	0.00 (100, 1110)				.965
No	4506	170 949	0.51 (.36, .73)				
Yes	231	4665	0.63 (.27, 1.43)				
Neurological disease	6.01	4000	0.03 (.87, 1.43)				.016
No	4410	164 650	0.64 (.45, .90)				.010
Yes	327	10 964	0.18 (.06, .57)			5	
Malignancy in the prior year	321	10 904	0.10 (.00, .37)				.387
	4559	174 090	0.56 (.40, .78)				.307
No							
Yes	178	1524	0.44 (.13, 1.51)				0.42
Immunosuppression					100		.042
No	4421	174 400	0.65 (.46, .92)		_	7	
Yes	316	1214	0.29 (.13, .68)				
					Paxlovid better	Paxlovid worse	
				-	1 1		
				0.1	0.33 0.5	1 2 3	

Nirmatrelvir with ritonavir (Paxlovid)



Effectiveness of Paxlovid in Reducing Severe Coronavirus Disease 2019 and Mortality in High-Risk Patients

Nirmatrelvir with Ritonavir (Paxlovid)

- Drug-drug interactions
 - Ritonavir component CYP-450 inhibition
 - <u>COVID-19 Drug Interactions website</u>
- 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
 - o 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

THE LANCET Infectious Diseases

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



The NEW ENGLAND JOURNAL of MEDICINE



NEJM: Remdesividir for the Treatment of COVID-19





The NEW ENGLAND JOURNAL of MEDICINE

3 consecutive days of IV RDV resulted in an 87% relative reduction in the risk of hospitalization or death when compared to placebo.

Gottlieb RL, Vaca CE, Paredes R, Mera J, Webb BJ, Perez G, Oguchi G, Ryan P, Nielsen BU, Brown M, Hidalgo A, Sachdeva Y, Mittal S, Osiyemi O, Skarbinski J, Juneja K, Hyland RH, Osinusi A, Chen S, Camus G, Abdelghany M, Davies S, Behenna-Renton N, Duff F, Marty FM, Katz MJ, Ginde AA, Brown SM, Schiffer JT, Hill JA; GS-US-540-9012 (PINETREE) Investigators. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. N Engl J Med. 2022 Jan 27;386(4):305-315. doi: 10.1056/NEJMoa2116846. Epub 2021 Dec 22. PMID: 34937145; PMCID: PMC8757570.

Remdesivir

Side Effects

Nausea, elevated transaminase levels, an increase in PTT, anaphylaxis

Baseline Labs

 $_{\circ}$ GFR, liver function, and prothrombin time tests

 $_{\circ}$ Discontinued if ALT increases to >10 times the upper limit of normal

Chronic Kidney Disease

 $_{\odot}$ Not to be used in patients with GFR ≤ 30 mL/min

• Pregnancy

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





The NEW ENGLAND JOURNAL of MEDICINE

Molnupiravir reduced the rate of hospitalization or death among patients by 31% compared to placebo.

Molnupiravir for Oral Treatment of Covid-19 in Nonhospitalized Patients

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

 $_{\rm O}$ 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
 - Obesity BMI >30
 - Physical Inactivity
 - $_{\circ}$ Age >50 years
 - $_{\circ}$ 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.
 - 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.



3 Steps to Initiating/Continuing Conversations

2

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?"

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."

Find common goals

3

"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.



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.





2

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







Treatments are very effective.

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







Rebound is often misunderstood.

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





5 Have questi

Have questions? Please ask.

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

2

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." 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. Offer more information

3

Offer <u>COVID-19 Treatment</u> Patient Education.



"Where Can I Learn More?"

- COVID-19 Therapeutics Warmline
 - 1-866-268-4322 (1-866-COVID-CA)
 - \circ 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 <u>here</u>
- Frequently Asked Questions document for clinics, providers, and pharmacists
- The CCI/CDPH Test to Treat Resource Hub can be found here: <u>https://www.careinnovations.org/covid-19-therapeutic-information/</u>

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 <u>rachel.jacobs@cdph.ca.gov</u>

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 Job Aid

COVID-19 Therapeutics Myths and Facts

How to dispel misinformation about treatments

MYTH:

I don't need medication for a mild-to-moderate illness.

PROVIDER ANSWER:

Lots of us are used to waiting out similar 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 symptoms develop into something more serious. The treatments can 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 don't think of ourselves as "high risk." However, there are many factors that can make even very healthy people more susceptible to becoming very ill from COVID-19. The truth is: the majority of adults fit into one of these categories. They include:

- 1. Anyone over age of 50.
- People living with diabetes, mental conditions (anxiety, depression, ADHD, and more), chronic lung disease (including asthma), chronic kidney disease, and cardiovascular disease.
- 3. People who are overweight, physically inactive, or who smoke.

 People who are negatively affected by social determinants of health, such as race, ethnicity, socio-economic status, or limited access to healthcare.

5. People who are unvaccinated 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

COVID-19 Therapeutics Myths and Facts:

MYTH:

Treatments have serious side effects.

PROVIDER ANSWER:

Of course, we all worry about side effects! Fortunately, most people have little-tono side effects. In clinical studies of Paxlovid, side effects occurred for less than 10% of patients. The most common side effect of Paxlovid is an unpleasant taste in the mouth, which occurred for 6% of people; smaller percentages of people have experienced diarrhea (3%), hypertension (1%), and/or muscle aches (1%).

Abdominal pain and general malaise have also been noted outside of clinical studies. Some other medications may need to be adjusted while you are taking Paxlovid. If you cannot take Paxlovid for any reason, you may be offered molnupiravir (Lagevrio) instead. Molnupiravir has very few side effects, but you cannot take it if you are pregnant.

MYTH: Rebound caused by treatments is common and can be dangerous.

PROVIDER ANSWER:

Rebound has been in the news a lot! The thing that most people don't realize is that viral rebound happens in people who don't take treatments as well as those who do, and less than 1 in 5 people experience rebound. It does happen somewhat more frequently among people who take Paxlovid. For some people, taking Paxlovid will help you test negative sooner. But for some, the symptoms may return. The good news is that if your symptoms do return, they tend to be mild and do not require repeating the treatment.

HELPFUL RESOURCES FOR PROVIDERS:

COVID-19 Therapeutics Decision Aid (hhs.gov)
 Underlying Medical Conditions Associated with Risk for Severe COVID-19 | CDC
 Information Sheet: Paxlovid Eligibility and Effectiveness (hhs.gov)
 Have questions? Email COVIDRxProviders@cdph.ca.gov



January 2023 • © 2023, California Department of Public Health

Resources



Join **#ThisIsOurShot / #VacunateYa** for newsletters about COVID-19 and vaccine-related talking points, and social media tips for physicians: <u>https://thisisourshot.info/</u> / <u>https://vacunateya.com/</u>



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



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. <u>https://www.healthdefend.com/</u>

COVID-19 Therapeutics: Resources and Support



Type of Support		Description	Updated 2.21.23	PublicHealth
	Clinical Guidance	health care providers to access left after hours will be returned	ne: 1-866-268-4322 (866-COVID-CA) is a real time resc s clinical consultation Monday through Friday 6 am – on the next business day.) You will be able to speak to tional Clinician Consultation Center.	5 pm. (Messages
_			bage (provides general information for healthcare provides facts sheets, and additional resources)	ders, allocations,
	General Information	<u>CDPH COVID-19 Treatn</u> therapeutics)	nents Job Aid (questions and answers for the public on	COVID-19
		COVID-19 Therapeutics Best Pract	ices Checklist (testing, prescribing, dispensing, and mo	re)
		Frequently Asked Questions docum	nent for clinics, providers, and pharmacists	
	Locating Resources	Finding Providers and Test-to-Trea	t Sites	
		 <u>COVID-19</u> Therapeutics Locate 	<u>or (</u> arcgis.com) or call 1-800-232-0233 (TTY 888-720-74	489)
		 <u>Test-to-Treat</u> (hhs.gov) 		
A @A	Questions	For general CDPH Therapeutics q	uestions, please email <u>COVIDRxProviders@cdph.ca.gc</u>	<u>vc</u>
\sim		For ordering, program inquiries, sig	gning up new HPoP Accounts: please e-mail <u>CDPHThe</u>	rapeutics@cdph.ca.gov

California Providers Stay Informed! To be added to CDPH messaging services is as easy as 1-2-3!



COVID-19 Vaccine Provider Listserv Emails: Please email <u>blanca.corona@cdph.ca.gov</u>

3

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

	mpox	News	letter S	ign Up	
First Na	me*				
Last Nar	me*				
Email*					
Organiza	ation/Clinic*				
Role/Titl	e				
Sign up	to the followi	ng newslette	ers:		
🗹 mn	ox-Providers	: H & e	adershin		

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



