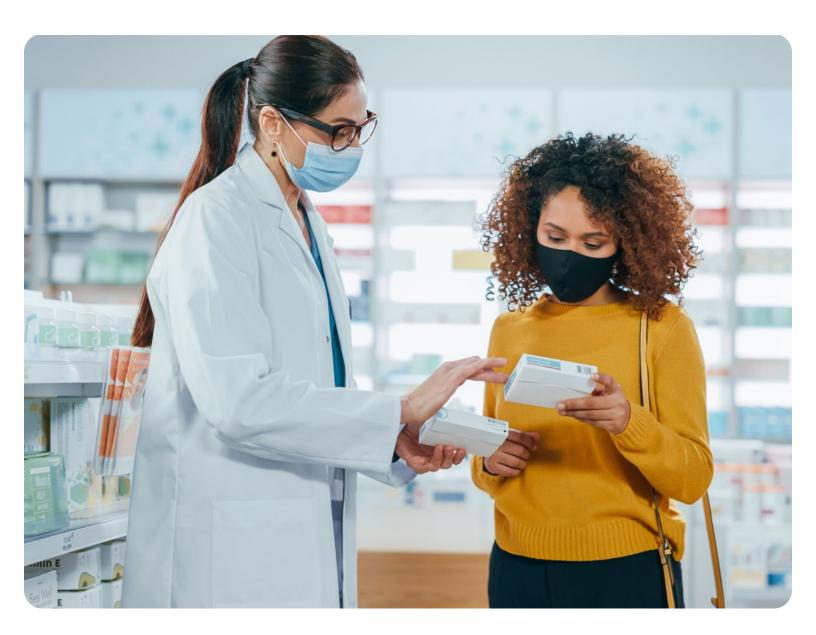




The Who, What, Where and When of COVID-19 Treatments: Everything You Need to Know About Lifesaving Antivirals

Webinar Follow Up Questions & Answers



POST-WEBINAR QUESTIONS ANSWERED BY OUR SPEAKERS:

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Dr. James Coleman Jr. Chief Executive Officer, G. A. Carmichael Family Health Center

<u>Julia Skapik MD, MPH, FAMIA</u> Chief Medical Information Officer, <u>National Association of Community Health Centers (NACHC)</u>

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Lisa Waddell, MD, MPH Chief Medical Officer, CDC Foundation (moderator)

Many community-based organizations supporting pandemic efforts are struggling to ensure the most impacted and at-risk people have information about and access to life-saving COVID-19 antivirals. Speakers from the CDC Foundation and Vaccine Equity Cooperative's <u>"The Who, What, Where and When of COVID-19 Treatments: Everything</u> <u>You Need to Know About Lifesaving Antivirals</u>" webinar answer additional questions on COVID-19 Antiviral Treatments below.

COVID-19 Antiviral Treatments: Additional Questions and Answers

Is there a trade name for "bebtelovimab"?

Yes, it's the trade name from Lilly.

Should someone who reacted badly to their first COVID infection be quicker to seek paxlovid if they are reinfected?

Persons with diagnosed COVID who have a clinical indication for treatment should seek out treatment, including with Paxlovid, as soon as possible. The benefit of antivirals is maximized by starting as soon as possible.

Do the guidelines for treatment change if a person has diabetes? I was told by a patient, she could not be treated due to drug interactions with her current medications to treat her chronic illnesses. Even though she had symptoms and presented within two days with a positive test (rapid) and confirmed PCR.

The choice of treatment should be made in consultation with a healthcare provider familiar with the patient's medical history and who can review their medications for any potential for drug-drug interaction with available choices to treat COVID-19, including Paxlovid. There should be few in any patients for whom at least one of the four currently available treatments for COVID-19 could be used.

What are the indications for use of dexamethasone?

Steroids like dexamethasone are presently indicated for use only for certain patients requiring hospitalization. For further details, refer to the National Institutes of Health's <u>Therapeutic Management of Hospitalized Adults</u> <u>With COVID-19</u> guidelines.

Can someone estimate the therapeutic index of these regimens? Need to know the margin of safety vs. efficacy.

These drugs were approved for emergency use by the FDA. Criteria for issuance of an EUA for a drug require:

- The condition to be treated is a serious or life-threatening disease.
- There is evidence the drug may be effective to treat this condition.
- A risk-benefit analysis indicates the potential or known benefits of the drug outweigh the potential of known risks.
- There are no alternatives based either on the absence of any other drug or insufficient supply of known alternatives.

Are the drug-drug interactions based on pairwise combinations? Some high-risk elderly are on many types of drugs. Any combination should be considered new entities.

Available data on drug-drug interactions are in a pairwise fashion (one drug to one drug). Healthcare providers need to consider the totality of potential and known interaction of all the patient's drugs when deciding how to proceed clinically with COVID-19 treatment. Consultation with a pharmacist is recommended for complex cases.

For rebound cases are people testing negative and then positive? Like a second period of positivity? Or is rebound referring to continuous positivity but feeling better then getting worse?

<u>COVID-19 rebound</u> is defined as recurrence of symptoms or a new positive viral test after having tested negative.

Should we refer each person who has tested positive or is it only those individuals with other chronic illness/high risk patients?

It depends on how well you know the medical history of the person who has tested positive. If referring to all patients, it may be helpful to temper expectations and alert them that Paxlovid and other COVID-19 treatments are indicated for people at high risk of complications or death if infected (i.e., with certain high-risk underlying medical conditions).

Why do they have to be taken within X days of symptoms?

The time within which people are recommended to start treatment is based on what was done in the study.

What if someone believed they barely woke up with a scratchy throat, several days prior to experiencing an actual sore throat? Would their eligibility for treatment start from the first event or the second?

That's a little complicated. I would say the first symptoms where you are sure it was something related to COVID and not something else, like an allergy. For instance, we have a cat and of course I'm allergic! So for me, some nose stuffiness and scratchy throat is due to the cat unless proven otherwise. For me, if I then got a sore throat, I'd start counting from the sore throat.

Can you briefly describe in general the mechanism/pharmacokinetics of how antivirals work on COVID-19? Especially in relation to "COVID rebound."

The small molecules drugs (all but bebtelovimab) work by blocking enzymes important for the virus to replicate. SO they stop the virus from growing and spreading. Bebtelovimab is an antibody that sticks to the virus and tags it for destruction by your immune system. Why some people get rebound isn't fully understood. But a leading hypothesis is that the immune system in people with rebound may be taking a little longer to get the virus under control.

Any recommendations for the renal function study results in order to prescribe paxlovid?

It is recommended that you assess the patient's GFR. This can be calculated using the blood level of creatinine, a routine blood test for kidney function. If the person is in care with a primary care provider, their GFR or recent creatinine levels is likely recorded in their medical record. Many providers check this measure frequently as part of routine health care. If needed, it can be checked with a blood test that can be run and reported out in a few hours if needed and depending on the facility and the lab they use. There are even some point-of-care options where if available, the creatinine can be measured from a small blood sample on the spot. Ask your doctor or pharmacist what may be available for you.

What are the requirements for prescription? What if your symptoms worsen but because you are deemed too young and with no comorbidities you don't qualify?

Your healthcare provider can help you determine if you meet criteria for Paxlovid or another outpatient medication.

What are the requirements to be a Test to Treat site? Can coalitions of local health departments, Federally Qualified Health Centers and hospitals be a joined partner?

- Sites must be able to provide comprehensive end-to-end test and treat services to support a seamless
 patient experience:
 - COVID-19 testing on-site (or evaluation of at-home testing)
 - Linkage to a clinical evaluation by licensed health care provider after positive result to provide prescription when appropriate
 - · Co-located or affiliated pharmacy able to readily dispense medication to eligible patients
- · Provide services to all individuals, regardless of insurance status
- Accept new patients for priority same-day or next-day visit for COVID-19 services

Can you share the report on who's being prescribed treatment? We have been looking for local data but would be interested in data by state if available.

See the CDC's MMWR report on equitable paxlovid distribution to learn more.

What is the difference between mAbs and remdesivir?

Remdesivir is a small molecule that goes inside the virus and blocks the action of enzymes it needs to replicate and thus slows down and halts the virus that way. mAbs are big molecules that stick to the virus and tag it so the immune system can come in with special cells that can kill the virus and block the virus' ability to bind to cells and infect them.

How do we sign up to be a Test to Treat location?

Reach out to your state COVID-19 response leadership to let them know you're interested. Make sure you meet all of the <u>Test to Treat (T2T) criteria</u>. From there, if your state agrees that you be an appropriate site, they would reach out to their Regional Emergency Coordinator to facilitate.

Could you outline why young people who are very ill, with no comorbidities, are turned away from receiving Paxlovid?

More people may be eligible than you realize. The FDA label notes that the drug is for the treatment of mild-tomoderate COVID-19 in people who are at high risk for progression to severe COVID-19, including hospitalization or death. So what qualifies as a condition that puts you at higher risk? The CDC has a pretty long list that includes some very common conditions like obesity, hypertension, and asthma. We know that Paxlovid given to persons who are not at high risk doesn't further improve their already very low risk of hospitalization compared with getting no drug. Ultimately, the decision to prescribe is at the discretion of the healthcare provider. If the person is severely ill, it may be better to bring them into the hospital. If they have really severe symptoms but are stable, the healthcare provider may focus on alleviating symptoms.

So treatments may be available for uninsured but not for undocumented immigrants?

Health centers treat patients regardless of whether they are documented. The same treatment is available to everyone. Learn more about coverage from the <u>Center on Budget and Policy Priorities</u>.

Is it prudent to wait at least a few days before starting Paxlovid to avoid rebound? Even in a 'high risk' age/ obesity with very few symptoms?

The benefit of antivirals is maximized by starting as soon as possible.

How will we know who is eligible for test-to-treat? Should we refer each person who has tested positive or is it only those individuals with other chronic illness/high risk patients?

Recent evidence shows that there is no benefit of Paxlovid for low-risk patients (study concluded early due to no benefit). Therefore we want to focus on treating high-risk patients but that is a large proportion of patients because obesity and age >50 are risk factors as are most chronic diseases seen commonly in the US.

Vaccine Equity Cooperative

About The Vaccine Equity Cooperative

The Vaccine Equity Cooperative supports local community-based workforces and other caregivers who are often the most trusted messengers and most skilled in navigating the individual histories and perspectives that impact vaccine readiness.

Our goal is to make it easier for people working in communities to access the most useful, relevant, and up-to-date information and tools for learning and communicating about the COVID-19 vaccine.

Learn more about the Vaccine Equity Cooperative and get involved at vaccineequitycooperative.org/get-involved



The CDC Foundation is partnering with the Vaccine Equity Cooperative to conduct webinars for communitybased organizations and their partners. View the entire <u>webinar series</u> on YouTube.