FDA Authorizes Pharmacists to Prescribe Oral Antiviral Medication for COVID-19

Joan Stephenson, PhD

The US Food and Drug Administration (FDA) has revised the Emergency Use Authorization (EUA) for nirmatrelvir/ritonavir, commonly known as Paxlovid, to allow state-licensed pharmacists to prescribe the medication to eligible patients with COVID-19 who are at high risk of progressing to severe disease, with certain limitations. The action is expected to widen access to the drug during the brief period after the onset of symptoms when it is effective.

"Since Paxlovid must be taken within 5 days after symptoms begin, authorizing state-licensed pharmacists to prescribe Paxlovid could expand access to timely treatment for some patients who are eligible to receive this drug for the treatment of COVID-19," Patrizia Cavazzoni, MD, director of the agency’s Center for Drug Evaluation and Research, said in a statement.

Paxlovid, which consists of 2 oral antiviral drugs (nirmatrelvir and ritonavir) taken together, is authorized for individuals aged 12 years or older who test positive for SARS-CoV-2 on a rapid at-home antigen test or a polymerase chain reaction test and are at high risk for progression to severe illness.

The FDA notes that because liver problems have occurred in patients receiving ritonavir, "caution should be exercised when administering Paxlovid to patients with pre-existing liver diseases, liver enzyme abnormalities, or hepatitis." The agency also says that the medication is not recommended for patients with severe kidney problems, and that patients with moderate kidney impairment require an adjustment in the dose.

The FDA’s original EUA for Paxlovid was issued in December 2021, with physicians, advanced practice registered nurses, and physician assistants authorized to prescribe the medication. However, it became apparent that many patients who would potentially benefit from Paxlovid faced hurdles—access to timely COVID-19 testing, to a clinician who could prescribe the drug, and to the pills themselves (which were initially in short supply)—that would prevent them from obtaining the drug within the 5-day window after onset of symptoms.

In March 2022, the Biden administration launched a nationwide COVID-19 "test to treat" initiative to increase timely access to Paxlovid. Under this program, people can go to "One-Stop Test to Treat" sites at pharmacy-based clinics, federally funded health centers, long-term care facilities, and community-based sites to be tested for COVID-19. Individuals who test positive can receive—if treatment is appropriate for them—a prescription from a health care professional on site or through telehealth and have their prescription filled at the same location.

Although some pharmacies have clinicians on staff with prescribing privileges, such as physicians and advanced practice registered nurses, the majority do not. Pharmacist professional groups advocated for the federal government to include US pharmacists as prescribers of oral COVID-19 antivirals. The American Pharmacists Association (APhA) said that its analysis of COVID-19 Test to Treat sites found that only 838 such sites had been established in the more than 28,000 community pharmacies located in federally recognized underserved communities, and that allowing pharmacists to order oral COVID-19 antivirals "will open up significantly more community pharmacies as one-stop points of care and increase equitable access to those who need it most."

"Removing barriers to pharmacist prescribing of oral antivirals has the potential to be a game-changer for addressing health equity and providing timely access to these life-saving treatments in pockets of the country where pharmacists may be the only health care provider for miles—just as it has been for the administration of COVID-19 vaccines," said APhA interim executive vice president and CEO Ilisa B. G. Bernstein, PharmD, JD, in a statement.

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Bernstein, who previously was deputy director of the Center for Drug Evaluation and Research’s Office of Compliance at the FDA, added that “this effort will only be successful and sustainable if [the Centers for Medicare & Medicaid Services] and other payers take immediate action to provide adequate and appropriate payment for pharmacist consultations and services.”

The FDA said that patients who test positive for COVID-19 should first consider seeking care from their regular health care clinician or seek a Test to Treat site in their area. The agency’s announcement said that at locations where state-licensed pharmacists are authorized to prescribe Paxlovid, pharmacists will require access to a patient’s recent electronic or printed health records (less than 12 months old), including the most recent reports of laboratory blood work (either from the patient or through a consult with the patient’s physician), to review for kidney or liver problems.

Also, to rule out the possibility of potentially serious drug interactions with Paxlovid, the pharmacist should also be provided with a list of all medications the patient is taking, the FDA said. The agency also noted that the pharmacist should refer patients for clinical evaluation with a clinician who is licensed or authorized under state law to prescribe drugs if the pharmacist does not have sufficient information to assess kidney and liver function or to identify a potential drug interaction. Patients also should be referred if other medications need to be modified because of a potential interaction or if it would not be feasible to perform recommended monitoring for a potential drug interaction.

Some physician groups expressed concerns that the FDA authorizing state-licensed pharmacists to prescribe Paxlovid has potential pitfalls. For example, the FDA’s recommendation of placing the responsibility on the patient to gather and present their own medical records to a pharmacist is “less than optimal in a real-world environment, especially when that patient is dealing with an acute illness,” said Ryan Mire, MD, president of the American College of Physicians, in a statement.

Although the majority of COVID-19–positive patients will benefit from Paxlovid, the medication is not for everyone, American Medical Association president Jack Resneck, Jr, MD, said in a statement, adding that prescribing it “requires knowledge of a patient’s medical history, as well as clinical monitoring for side effects and follow-up care to determine whether a patient is improving—requirements far beyond a pharmacist’s scope and training.”

ARTICLE INFORMATION

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Corresponding Author: Joan Stephenson, PhD, Contributing Editor, JAMA Health Forum (Joan.Stephenson@jamanetwork.org).

Author Affiliation: Contributing Editor, JAMA Health Forum.

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