July 6, 2022

The U.S. Food and Drug Administration's (FDA or Agency) Intergovernmental Affairs (IGA) team would like to share an important update with you. Today, FDA revised the Emergency Use Authorization (EUA) for Paxlovid (nirmatrelvir and ritonavir), to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid. Read more below.

Coronavirus (COVID-19) Update: FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations

New Prescribing Authority Could Improve Access for Some Patients at High Risk for Severe COVID-19

"The FDA recognizes the important role pharmacists have played and continue to play in combatting this pandemic," said Patrizia Cavazzoni, M.D., director for the FDA's Center for Drug Evaluation and Research. "Since Paxlovid must be taken within five 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."

When testing positive for COVID-19, patients should first consider seeking care from their regular health care provider or locating a Test-to-Treat site in their area. While this action allows state-licensed pharmacists to prescribe Paxlovid with certain limitations as described below, community pharmacies not already participating as a Test-to-Treat site can decide if or how they will offer this service to patients.

Patients who have tested positive for COVID-19 and are seeking to determine their eligibility for receiving Paxlovid at locations where prescribing by state-licensed pharmacists is available should bring the following information to ensure that the state-licensed pharmacist has sufficient information to determine their eligibility to receive Paxlovid:

- Electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work for the state-licensed pharmacist to review for kidney or liver problems. State-licensed pharmacists could also receive this information through a consult with the patient's health care provider.
- A list of all medications they are taking, including over-the-counter medications so the state-licensed pharmacist can screen for drugs with potentially serious interactions with Paxlovid.

Under the limitations outlined in the authorization, the state-licensed pharmacist should refer patients for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is needed due to a potential drug interaction.
- Paxlovid is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progression to severe

COVID-19, including hospitalization or death. Patients in the authorized population who report a positive home test result from a rapid antigen diagnostic test, or a positive PCR test, to their provider are eligible for Paxlovid under the EUA. Confirmation of a positive home rapid antigen diagnostic test with additional direct SARS-CoV-2 viral testing, such as a PCR, is not required. Antibody tests are not considered to be direct SARS-CoV-2 viral tests.
Additional Resources:

- Paxlovid EUA Letter of Authorization
- Frequently Asked Questions on the Emergency Use Authorization for Paxlovid
- FDA Updates on Paxlovid for Health Care Providers
- Emergency Use Authorization: Drugs and Non-Vaccine Biological Products
- Coronavirus Disease (COVID-19)
- Coronavirus Treatment Acceleration Program (CTAP)
- Test to Treat Locator
- COVID-19 Therapeutics Locator