



NOTICE TO HEALTH FACILITIES: FDA AUTHORIZES PHARMACISTS TO PRESCRIBE PAXLOVID WITH CERTAIN LIMITATIONS

July 14, 2022

Paxlovid (nirmatrelvir & ritonavir) 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 kg. [88 lbs.]) with positive results of direct SARS-CoV-2 viral testing, within the first five (5) days of symptom on-set, who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid **is not authorized** for hospitalized patients due to COVID-19, pre-exposure or post-exposure prophylaxis for prevention of COVID-19, nor for use longer than five (5) consecutive days.

On July 6, 2022, the U.S. Food and Drug Administration (FDA) revised the Emergency Use Authorization for Paxlovid to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations. In doing so, the FDA stated

“The FDA recognizes the important role pharmacists have played and continue to play in combatting this pandemic.... 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.”

The requirements established by the FDA’s authorization so that state-licensed pharmacists may prescribe Paxlovid to eligible patients are as follows:

A. Eligibility

A patient is eligible when he has tested positive for COVID-19. (Please note: when testing positive for COVID-19, a patient **should first** consider seeking care from their regular health care provider or locating a test-to-treat site).¹

¹ See <https://aspr.hhs.gov/TestToTreat/Pages/default.aspx>. While this action allows state-licensed pharmacists to prescribe Paxlovid with certain limitations, community pharmacies that are not participating as a *test-to-treat* site can decide if or how they will offer this service to patients.

B. Requirements

1. Patients who have tested positive for COVID-19 and are seeking to determine their eligibility for receiving Paxlovid, should bring the following information to ensure that the state-licensed pharmacists have 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 pharmacists to review for kidney or liver problems.²
 - A list of all medications they are taking, including over-the-counter medications so the state-licensed pharmacists can screen for drugs with potentially serious interactions with Paxlovid.

C. Patient Evaluation

Every pharmacist to prescribe Paxlovid to an eligible patient must first evaluate the following:

1. History of significant hypersensitivity reaction to the active ingredient (nirmatrelvir or ritonavir) or any other components.
2. The co-administration with drugs highly dependent on CYP3A and co-administration with potent CYP3A inducers, where significantly reduced nirmatrelvir or ritonavir plasma concentration may be associated with the potential for loss of biologic response and possible resistance.
3. The co-administration of Paxlovid can alter the plasma concentration of other drugs and *vice-versa*. It is mandatory to consider the potential for drug interactions prior to and during Paxlovid therapy.

For full prescribing information prior to and during treatment please refer to <https://www.fda.gov/media/155050/download>.

If any of the following circumstances apply, the state-licensed pharmacists should refer the patient for clinical evaluation with a physician:

- 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, or

² State-licensed pharmacists could also receive this information through a consult with the patient's health care provider.

- 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.

If you have any questions or concerns you may contact SARAFS at (787) 765-2929, ext. 4770, or via an email (tratamientoantiviralespr@salud.pr.gov)

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