**Can Kentucky licensed pharmacists prescribe PAXLOVID for patients with a COVID-19 diagnosis?**

Yes, Kentucky licensed pharmacists can prescribe PAXLOVID despite conflicting state law not giving pharmacists the authority to independently prescribe medication. Under the FDA's Emergency Use Authorization (EUA) issued on July 6, 2022, state-licensed pharmacists can independently prescribe PAXLOVID. As stated in FDA's Emergency Use Authorization of Medical Products and Related Authorities Guidance, "FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564."

**What clinical information must be reviewed prior to prescribing PAXLOVID?**

1. Sufficient information, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function.
2. Sufficient information, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and nonprescribed) that the patient is taking to assess for potential drug interaction.

**Are there limitations on when PAXLOVID can be prescribed?**

Yes, the use of PAXLOVID must be in accordance with the authorized Fact Sheets.

- Moreover, PAXLOVID is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.
- PAXLOVID is not authorized for use for longer than 5 consecutive days.
- PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19. Patients reporting shortness of breath or difficulty breathing should be referred for immediate medical assessment to evaluate whether the illness has progressed to the severe stage and may require hospitalization.
- PAXLOVID is not authorized for the treatment of severe COVID-19.

**What patients should be treated with PAXLOVID?**

The EUA for emergency use of PAXLOVID is limited to the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Mild-to-moderate COVID-19 can be determined by patient self-report of symptoms.

**When should a patient be referred for a clinical evaluation?**

The licensed pharmacist should refer patients for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant 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.

**When should PAXLOVID be administered to a patient?**
PAXLOVID treatment should be initiated as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.

**Is PAXLOVID FDA-approved to prevent or treat COVID-19?**
No. it is not FDA-approved to prevent or treat any diseases or conditions, including COVID-19. PAXLOVID is an investigational drug.

**Are there reporting requirements for health care facilities and providers as part of the EUA?**
Yes. As part of the EUA, FDA requires health care providers who prescribe PAXLOVID to report all medication errors and serious adverse events considered to be potentially related to PAXLOVID through FDA's MedWatch Adverse Event Reporting program. FDA MedWatch forms should also be provided to Pfizer. Health care facilities and providers must report therapeutics information and utilization data as directed by the U.S. Department of Health and Human Services.

**Do patient outcomes need to be reported under the EUA?**
No, reporting of patient outcomes is not required under the EUA.

**Are licensed pharmacists able to prescribe both the regular and renal doses of PAXLOVID?**
Yes, provided the state-licensed pharmacist has adequate information to assess renal function and the patient otherwise meets the eligibility criteria for receiving PAXLOVID under the EUA.

**How long will Kentucky-licensed pharmacist be authorized to prescribe PAXLOVID?**
For as long as the Emergency Use Authorization is in effect.