



Frequently Asked Questions on the Emergency Use Authorization for Paxlovid for Treatment of COVID-19

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Questions related to Paxlovid's approval and EUA

Q. Now that Paxlovid is FDA-approved, and the commercial product is available, what does the EUA for Paxlovid authorize?

A. The EUA for Paxlovid continues to authorize Paxlovid for the treatment of pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. The clinical development of Paxlovid for pediatric use is ongoing. As of March 9, 2024, only Paxlovid manufactured and labeled in accordance with the approved New Drug Application 217188 (NDA-labeled Paxlovid) may be dispensed.

The EUA for Paxlovid also continues to authorize the prescribing of Paxlovid for an individual patient by a state-licensed pharmacist 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) who are at high risk for progression to severe COVID-19, including hospitalization or death, in accordance with the FDA-approved Prescribing Information or authorized labeling, as applicable, and subject to certain conditions as detailed in the Letter of Authorization and the authorized Fact Sheet for Health Care Providers.

Q. Is Paxlovid manufactured and labeled in accordance with the EUA (EUA-labeled Paxlovid) still authorized for emergency use?

A. No. In January 2024, FDA revised the Paxlovid EUA to state that EUA-labeled Paxlovid would no longer be authorized at the time of the labeled or extended expiry, as applicable, or through March 8, 2024, whichever is earlier. On March 13, 2024, FDA further revised the Paxlovid EUA to incorporate conforming changes consistent with this earlier revision.

EUA-labeled Paxlovid is no longer authorized for emergency use, regardless of the labeled or extended expiration date. All EUA-labeled Paxlovid, including expired EUA-labeled Paxlovid, remaining in U.S. distribution must be returned to the manufacturer or disposed of in accordance with all federal, state, and local regulations.

As of March 9, 2024, only Paxlovid manufactured and labeled in accordance with the approved New Drug Application 217188 (NDA-labeled Paxlovid) may be dispensed.

Q. What are the FDA-approved uses for Paxlovid?

A. On May 25, 2023, FDA approved [Paxlovid](#) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. FDA has determined that Paxlovid is safe and effective when used in accordance with the FDA-approved labeling.

Q. Paxlovid is approved and authorized only for certain patients at “high risk”. What does “high risk” mean?

A. Determining whether a patient is at high risk for progression to severe COVID-19, including hospitalization or death, is based on the provider's assessment of the individual patient being considered for treatment with COVID-19 and that patient's medical history.



Resources providing information on conditions that place a patient with mild-to-moderate COVID-19 at high risk for disease progression, including hospitalization or death, can be found at the Centers for Disease Control and Prevention site: [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals](#)

Q. How can Paxlovid be obtained?

A. For questions on how to obtain NDA-labeled Paxlovid, please visit the [Pfizer website](#). Through December 31, 2024, eligible patients qualify for free Paxlovid through the [PAXCESS program](#). Eligible patients include Medicare beneficiaries, Medicaid beneficiaries, and uninsured individuals who do not have a prescription drug benefit at the time they fill their prescription. Patients who are commercially insured may be eligible for assistance through a co-pay savings program.

Questions for pharmacist prescribers

Q. Are pharmacists permitted to prescribe Paxlovid?

A. In addition to any health care provider licensed or authorized under state¹ law to prescribe drugs, the EUA for Paxlovid continues to authorize prescribing of Paxlovid for an individual patient by a state-licensed pharmacist 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) who are at high risk for progression to severe COVID-19, including hospitalization or death, in accordance with the FDA-approved Prescribing Information or authorized labeling subject to the following conditions:

- Sufficient information is available, 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; and
- Sufficient information is available, 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 non-prescribed) that the patient is taking to assess for potential drug interaction.

The state-licensed pharmacist should refer an individual patient for clinical evaluation (e.g., telehealth, in-person visit) 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 authorized Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

¹ The term “State” includes any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. See Section 201(a)(1) of the Act.



Q. What do state-licensed pharmacist prescribers need to do to assess whether the patient is at high risk for progression to severe COVID-19, including hospitalization or death?

A. State-licensed pharmacist prescribers have the same requirements as all other prescribers to determine that an adult or pediatric patient (12 years of age and older weighing at least 40 kg), who is being considered for treatment with Paxlovid, has a diagnosis of mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

A review of reported symptoms should be completed to determine that patients have signs and symptoms consistent with mild-to-moderate COVID-19, and not severe COVID-19. Patients reporting shortness of breath or difficulty breathing should be immediately referred for further medical assessment to determine whether their illness has progressed to the severe stage, which may require hospitalization. In general, mild-to-moderate COVID-19 is symptomatic SARS-CoV-2 infection that is not severe enough to require hospitalization. Paxlovid is not authorized or approved for the treatment of severe COVID-19.

State-licensed pharmacist prescribers may determine whether an individual patient is at high risk for severe COVID-19 by obtaining a medical history from the patient or by accessing the patient's medical records. Resources about conditions that place a patient with mild-to-moderate COVID-19 at increased risk for disease progression or death can be found at the Centers for Disease Control and Prevention site: [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals](#).

Q. How do state-licensed pharmacist prescribers assess for potential drug interactions?

A. All prescribers are expected to utilize available health records or patient history to obtain a complete list of all medications (prescribed and non-prescribed) that the patient is taking. State-licensed pharmacists may also consult with a health care provider in an established provider-patient relationship with the individual patient to obtain a comprehensive list of medications the patient is taking. Resources to identify potential drug interactions include the approved Prescribing Information, the [Fact Sheet for Health Care Providers](#) and the [Prescriber Patient Eligibility Screening Checklist](#) available on the [FDA EUA webpage](#). Other resources include: the [IDSA COVID-19 Treatment Guidelines](#) and the [University of Liverpool COVID-19 Drug Interactions](#).

Should an adjustment to another medication be needed due to a potential drug interaction, the state-licensed pharmacist should refer the individual patient for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs.

Q. How do state-licensed pharmacist prescribers assess renal and hepatic function?

A. State-licensed pharmacist prescribers must have access to sufficient information from health records to assess renal and hepatic function. Health records include access to an electronic health record system containing this information in progress notes or laboratory records, reviewing a printed health record such as a laboratory report provided by the patient, or reviewing information in electronic health records the patient may have access to through a phone app or other means. Health records within the past 12 months are generally acceptable, provided there is no patient self-report or other information suggestive of kidney or liver disease. State-licensed pharmacists may also consult with a health care provider in an established provider-patient relationship with the individual patient to obtain this



information. If sufficient information is not available to assess renal and hepatic function, the state-licensed pharmacist should refer the individual patient to a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs.

Physicians, advanced practice registered nurses, and physician assistants may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of renal impairment. These providers may consider ordering a serum creatinine or calculating the estimated glomerular filtration rate (eGFR) for certain patients after assessment on a case-by-case basis.

Q. Will state-licensed pharmacists be able to prescribe both the standard and renal doses of Paxlovid?

A. Yes, the EUA authorizes state-licensed pharmacists to prescribe both the standard and renal doses of Paxlovid, subject to the terms and conditions on pharmacist prescribing as detailed in the EUA, provided the pharmacist has adequate information to assess renal function and the patient is otherwise eligible to receive Paxlovid.

General EUA-related questions

Q. What is an emergency use authorization (EUA)?

A. Under section 564 of the Federal Food, Drug & Cosmetic Act, after a declaration by the HHS Secretary based on one of four types of determinations, FDA may authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, FDA must determine, among other things, that based on the totality of scientific evidence available to the agency, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits of the product, when used to treat, diagnose or prevent such disease or condition, outweigh the known and potential risks of the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure.

Q. Are there reporting requirements for health care facilities and providers as part of the EUA (when Paxlovid is for emergency use as described in the Letter of Authorization)?

A. Yes. As a condition on the emergency use of Paxlovid (see section II "Scope of Authorization" in the LOA for Paxlovid), FDA requires health care providers who prescribe Paxlovid to report all medication errors and serious adverse events considered to be potentially related to the use of Paxlovid in the authorized pediatric population through FDA's [MedWatch Adverse Event Reporting](#) program. Providers can complete and submit the report [online](#); or download and complete the [form](#), then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA's [Fact Sheet for Health Care Providers](#). FDA MedWatch forms should also be provided to Pfizer.

Q. Do patient outcomes need to be reported under the EUA?

A. No, reporting of patient outcomes is not required under the EUA. However, reporting of all medication errors and serious adverse events considered to be potentially related to Paxlovid occurring during treatment is required.

Q. FDA has issued a number of EUAs including for therapeutics. If state laws impose different or additional requirements on the medical product covered by an EUA, are those state laws preempted?

A. 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.” The guidance explains the basis for FDA’s views on this subject.

Q. Can health care providers share the patient/caregiver Fact Sheet electronically?

A. Under the authorization, Pfizer must make available the authorized Fact Sheets on its website at: www.COVID19oralRX.com. Health care facilities and health care providers must ensure that fact sheets are made available to patients, parents, and caregivers through “appropriate means” and electronic delivery of the Fact Sheet is an appropriate means.