

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

### **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. What does this EUA authorize? What are the limitations of authorized use?**

**A.** The [EUA](#) authorizes the emergency use of the unapproved product Paxlovid (nirmatrelvir co-packaged with ritonavir) for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate coronavirus disease 2019 (COVID-19), who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is not approved for any use, including for the treatment of COVID-19.

Paxlovid is not authorized:

- for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- for use longer than five consecutive days.

### **Q. How is high risk defined under the EUA?**

**A.** Information 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](#) and at [NIH's COVID-19 Treatment Guidelines: Clinical Spectrum of SARS-CoV-2 Infection](#) Health care providers should consider the benefit-risk for an individual patient.

### **Q. Are there potential side effects of Paxlovid?**

**A.** Possible side effects of Paxlovid include dysgeusia (altered or impaired sense of taste), diarrhea, increased blood pressure, and myalgia (muscle aches). Allergic reactions, abdominal pain, nausea, and malaise (feeling generally unwell) have also been reported after Paxlovid use.

Nirmatrelvir and ritonavir, which comprise Paxlovid, also interact with other medicines, which may lead to serious or life-threatening adverse reactions. Patients should tell their health care providers all of the medicines they are taking, including over-the-counter medications and herbal supplements, when deciding whether to take Paxlovid.

Liver problems have occurred in patients receiving ritonavir. Therefore, caution should be exercised when administering Paxlovid to patients with pre-existing liver diseases, liver enzyme abnormalities, or hepatitis. Patients should talk with their health care provider if they have a history of liver problems.

Paxlovid is not recommended for patients with severe kidney problems, and a different dose is needed for patients with moderate kidney problems. Patients should talk with their health care provider if they have a history of kidney problems.

Because nirmatrelvir is co-administered with ritonavir, there may be a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection. Patients with HIV who are not on treatment with “undetectable” viral load should talk with their health care provider before taking Paxlovid.

There are limited clinical data available for Paxlovid. Serious and unexpected adverse events may occur that have not been previously reported with Paxlovid use.

**Q: Is Paxlovid FDA-approved to prevent or treat COVID-19?**

**A.** No. Paxlovid is not FDA-approved to prevent or treat any diseases or conditions, including COVID-19. Paxlovid is an investigational drug.

**Q. How can Paxlovid be obtained for use under the EUA?**

**A.** For questions on how to obtain Paxlovid, please contact [COVID19therapeutics@hhs.gov](mailto:COVID19therapeutics@hhs.gov).

**Q. Who may prescribe Paxlovid under the EUA?**

**A.** Paxlovid may be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs.

Paxlovid may also be prescribed for an individual patient by a state-licensed pharmacist under 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.

**Q. When should Paxlovid be administered to a patient?**

**A.** Patients should talk to their health care provider to determine whether, based on their individual circumstances, they are eligible to receive Paxlovid. Paxlovid treatment should be initiated as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.

More information about administration is available in the [Fact Sheet for Health Care Providers](#).

**Q: Does the EUA require a positive result from a direct SARS-CoV-2 viral test prior to prescribing Paxlovid to a patient who is at high risk for severe COVID-19?"**

**A:** No. The Agency removed the requirement for positive test results effective February 1, 2023. FDA recognizes that, in rare instances, individuals with a recent known exposure (e.g., a household contact) who develop signs and symptoms consistent with COVID-19 may be diagnosed by their health care provider as having COVID-19 even if they have a negative direct SARS-CoV-2 viral test result. In such instances, their health care provider may determine that treatment with Paxlovid for COVID-19 is appropriate if the patient reports mild-to-moderate symptoms of COVID-19 and is at high-risk for progression to severe COVID-19, including hospitalization or death, and the terms and conditions of the authorization are met, as detailed in the [Fact Sheet for Healthcare Providers](#).

The Agency continues to recommend that providers use direct SARS-CoV-2 viral testing to help diagnose COVID-19.

**Q: What does direct SARS-CoV-2 viral testing mean?**

**A:** Direct SARS-CoV-2 viral tests diagnose current COVID-19 infection. Direct SARS-CoV-2 viral tests include two types of diagnostic tests for COVID-19:

- Molecular tests, such as reverse transcription polymerase chain reaction (RT-PCR) tests, that detect the virus's genetic material.
- Antigen tests that detect specific proteins from the virus.

Antibody tests should not be used to diagnose COVID-19 and are not direct SARS-CoV-2 viral tests. Antibody tests look for antibodies that the immune system makes in response to the SARS-CoV-2 virus.

**Q. Does the EUA permit the use of Paxlovid for some hospitalized patients?**

**A.** Yes, Paxlovid is authorized for the treatment of patients hospitalized with mild-to-moderate COVID-19, such as patients admitted for monitoring of drug-drug interactions.

Paxlovid is also authorized for patients hospitalized for conditions other than COVID-19, provided the terms of the authorization are otherwise met.

Paxlovid is also authorized for patients who require hospitalization due to severe or critical COVID-19 **after** starting treatment with Paxlovid. These patients should complete the full 5-day treatment course per the healthcare provider's discretion.

**Q. Are there data showing Paxlovid may provide benefit for treatment of mild-to-moderate COVID-19 for certain patients?**

**A.** Yes. The primary data supporting this EUA for Paxlovid are from EPIC-HR, a randomized, double-blind, placebo-controlled clinical trial studying Paxlovid for the treatment of non-hospitalized symptomatic adults with a laboratory confirmed diagnosis of SARS-CoV-2 infection. Patients were adults 18 years of age and older with a prespecified risk factor for progression to severe disease or were 60 years and older regardless of prespecified chronic medical conditions. All patients had not received a COVID-19 vaccine and had not been previously infected with COVID-19. The main outcome measured in the trial was the proportion of people who were hospitalized due to COVID-19 or died due to any cause during 28 days of follow-up. Paxlovid significantly reduced the proportion of people with COVID-19 related hospitalization or death from any cause by 88% compared to placebo among patients treated within five days of symptom onset and who did not receive COVID-19 therapeutic monoclonal antibody treatment. In this analysis, 1,039 patients had received Paxlovid and 1,046 patients had received placebo and among these patients, 0.8% who received Paxlovid were hospitalized or died during 28 days of follow-up compared to 6% of the patients who received placebo. Of the people who received Paxlovid, no patients died within this time period compared to 12 people who received placebo.

Details on the clinical trial results can be found in Section 14 of the authorized [Fact Sheet for Health Care Providers](#).

**Q. Are there reporting requirements for health care facilities and providers as part of the EUA?**

**A.** 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. 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.

Health care facilities and providers must report therapeutics information and utilization data as directed by the U.S. Department of Health and Human Services.

**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](http://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.

**Q. What do state-licensed pharmacist prescribers need to do to determine whether a patient may be eligible to receive Paxlovid?**

**A.** State-licensed pharmacist prescribers have the same requirements as all other prescribers to assess an adult or pediatric patient (12 years of age and older weighing at least 40 kg), who is being considered for treatment with Paxlovid, to determine that they have a current 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. Paxlovid is not authorized for the treatment of severe COVID-19.

Definitions for mild and moderate illness are provided in [NIH’s COVID-19 Treatment Guidelines: Clinical Spectrum of SARS-CoV-2 Infection](#).

For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, prescribers should refer to the Centers for Disease Control and Prevention (CDC) website linked in the [Fact Sheet for Health Care Providers](#). 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.

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

**A.** Pharmacists have always played and will continue to play a critical role in identifying potential drug interactions with Paxlovid. 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 [Fact Sheet for Health Care Providers](#) and [Prescriber Patient Eligibility Screening Checklist](#) available on the [FDA EUA webpage](#). Other resources include: the [NIH COVID-19 Treatment Guidelines](#), 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 regular and renal doses of Paxlovid?**

**A.** 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.