



July 7, 2022

FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations

On July 6, 2022, the U.S. Food and Drug Administration 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.***¹

- 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 PCR, is not required. Antibody tests are not considered to be direct SARS-CoV-2 viral tests.

Limitations Outlined in the Authorization:^{1,2}

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.

Patient Eligibility:¹

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.

Resources:¹

- [Fact Sheet for Healthcare Providers](#)
- [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 \(COVID-19\)](#)

IHS Test to Treat Initiative.³

Effective March 7, 2022, the HHS Coordination Operations and Response Element, or HCore, began distributing oral antiviral pills directly to participating Test to Treat pharmacy-based clinics. HCore is providing the Indian Health Service with a supplemental allocation of the oral antiviral, in support of an IHS COVID-19 Test to Treat Initiative.

The IHS, in collaboration with tribal and urban Indian partners, operates a national system of health care that combines access to laboratory, medical, and pharmacy services in tribal communities. In order to promote access to COVID-19 outpatient treatment and reduce the burden of COVID disease in the American Indian and Alaska Native population, the IHS has recruited over 60 test-to-treat pilot sites, representing a range of regions, facility types, and demographics. Sites have completed a self-assessment to demonstrate access to laboratory, medical, and pharmacy services, and the development of protocols to facilitate COVID-19 testing and outpatient treatment with [Paxlovid](#).

Best practices, including protocols developed by the pilot sites, are being leveraged to support recruitment of new IHS sites in the intermediate term, with the goal to scale up COVID-19 test-to-treat operations IHS-wide in the coming months.

More information about the IHS Test to Treat Initiative, including the site self-assessment and attestation process, as well as best practices developed by current pilot sites, may be accessed on the [IHS National Pharmacy and Therapeutics Committee website](#).

References:

1. U.S. Food and Drug Administration. [FDA Authorizes Pharmacists to Prescribe Paxlovid With Certain Limitations](#). Published July 6, 2022.
2. U.S. Centers for Disease Control and Prevention. [Fact Sheet for Healthcare Providers](#). Last updated: Jul 6, 2022.
3. Indian Health Service. [IHS Test to Treat Initiative Promotes Access to COVID-19 Outpatient Treatment](#). Published June 23, 2022.