Indian Health Service
National Pharmacy and Therapeutics Committee
COVID-19 Emerging Treatments Update

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.