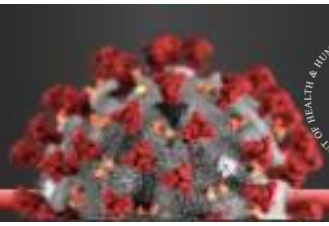
Indian Health Service
National Pharmacy and Therapeutics Committee
COVID-19 Emerging Treatments Update



February 6, 2023

FDA Revises Paxlovid, Molnupiravir EUAs Removing Positive COVID-19 Test Requirements

On February 1, 2023, the U.S. Food and Drug Administration (FDA) updated the Emergency Use Authorizations (EUAs) for Paxlovid™ (nirmatrelvir tablets; ritonavir tablets) and Lagevrio™ (molnupiravir), removing the requirement for positive SARS-CoV-2 test results prior to prescribing.

The update was made to cover instances where a health care provider might deem it appropriate to prescribe oral antiviral treatment to an individual with a recent known exposure who develops signs and symptoms consistent with COVID-19 and is at high risk for progression, but tests negative for the virus. Though no longer a requirement, the FDA continues to recommend direct SARS-CoV-2 testing to help diagnose COVID-19.

Paxlovid™ (nirmatrelvir tablets; ritonavir tablets) is authorized 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 COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Lagevrio™ (molnupiravir) is authorized for the treatment of adults with a current diagnosis of mild-to-moderate COVID-19:

- who are at high risk for progression to severe COVID-19, including hospitalization or death, and for
- whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate

Considerations and Interpretation of EUA Changes for IHS Providers:

The EUA revisions for the oral antivirals, Paxlovid™ and Lagevrio™ extend their authorized use to the relatively uncommon instances of suspected cases of symptomatic, test-negative COVID-19. No test is 100 percent sensitive and false negative results are known to occur. Sound clinical judgment by the prescribing provider is recommended in making determinations of treatment eligibility in the absence of a confirmatory lab test. Appropriate access to a prescription for oral antiviral medication should be balanced against over-prescribing for test-negative cases both to reduce the risk of viral resistance and side effects. The FDA continues to recommend direct SARS-CoV-2 testing to help diagnose COVID-19. The IHS continues to advocate a Test-to-Treat approach including rapid access to direct SARS-CoV-2 testing and early treatment with oral antivirals for patients with laboratory-confirmed and/or clinically suspected cases of COVID-19.

EUA Fact Sheets (*updated February 1, 2023*)

- Paxlovid®:
  - Healthcare Providers
  - Patients, Parents and Caregivers
  - PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers
  - Frequently Asked Questions on the EUA for Paxlovid for Treatment of COVID-19
- Lagevrio™:
  - Healthcare Providers
  - Patients, Parents and Caregivers
  - Dear Healthcare Provider Letter
  - Prescriber Checklist for Molnupiravir
  - Frequently Asked Questions on the EUA for Molnupiravir for Treatment of COVID-19

References:
1. MPR. FDA Revises Paxlovid, Lagevrio EUAS Removing Positive COVID-19 Test Requirement. Published online Feb 1, 2023.
2. US Food and Drug Administration. LAGEVRIO™ (molnupiravir) Letter of Authorization. Revised Feb 1, 2023.
3. US Food and Drug Administration. Paxlovid® Letter of Authorization. Revised Feb 1, 2023.