ASPR Administration for Strategic Preparedness & Response

Information Sheet - Paxlovid Eligibility and Effectiveness

- While vaccination continues to provide the best protection against COVID-19, therapies are widely available to help treat eligible people who do get sick and are at risk of developing severe disease.
- There is strong scientific evidence that antiviral treatment of outpatients at risk for severe COVID-19 reduces their risk of hospitalization and death.
- The antiviral drug **Paxlovid (ritonavir-boosted nirmatrelvir)** and Veklury (remdesivir), are the preferred treatments for eligible adult and pediatric patients with current diagnosis of mild-to-moderate COVID-19 and who are at risk for progression to severe COVID-19.
- COVID-19 treatments should be considered for any COVID-19 patient who meets the eligibility criteria.
- This information sheet summarizes current information about **Paxlovid** and offers resources about other COVID-19 therapeutics.

What is Paxlovid?

- Paxlovid (ritonavir-boosted nirmatrelvir) is a preferred oral antiviral authorized for the treatment of mild-moderate COVID-19 illness.
- Patients take a combination of pills twice a day for 5 days. Paxlovid should be administered as early as possible following the appearance of any symptoms and needs to be initiated within 5 days of symptom onset.

Who is eligible for Paxlovid?

- Paxlovid is for adults and children 12 and older who are at higher risk for developing serious COVID-19 disease that may lead to hospitalization and/or death. Paxlovid should be considered for any patients who meet the following criteria:
  - Have a current diagnosis of mild-to-moderate COVID-19 & are within 5 days of symptom onset, **AND**
  - Have one or more risk factors for severe COVID
- The U.S. Food and Drug Administration's (FDA) Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers can be used to assess eligibility.
- See the FDA's Fact Sheet for Healthcare Providers for detailed information about Paxlovid.

Who is considered to have a risk factor for severe COVID-19?

- Per the current CDC's Interim Clinical Considerations for COVID-19 Treatment in Outpatient guidelines, risk factors include:
  - Age 50 years or older, with risk increasing substantially at age ≥ 65 years
  - **Being unvaccinated or not being up to date on COVID-19 vaccinations**
  - **Specific medical conditions and behaviors**

Does Paxlovid work? Why prescribe a medication for mild-moderate COVID-19?

- The benefit of a 5-day treatment course of Paxlovid was demonstrated in the clinical trial that supported its Emergency Use Authorization (EUA). This study showed that among non-hospitalized, unvaccinated patients at high risk of progression to severe disease, treatment with **Paxlovid reduced the risk of hospitalization or death by 88%.**
- Observational data, including vaccinated patients, from Israel,[1] Hong Kong,[2] and the United States[3] is consistent with benefit in high-risk patients:
  - **46% reduction in hospitalizations and deaths compared to the untreated**[1]
  - **65% reduction in death compared to non-users**[2]
  - **51% lower hospitalization rate within 30 days after diagnosis than those who were not prescribed Paxlovid**[3]

References

[1]Ronza Najjar-Debbiny et al. Clinical Infectious Diseases, 2022; ciac443, https://doi.org/10.1093/cid/ciac443
[2]Carlos K.H. et al. *Lancet Infectious Disease* 2022; doi: https://doi.org/10.1016/S1473-3099(22)00507-2
[3] Shah et al. MMWR https://www.cdc.gov/mmwr/volumes/71/wr/mm7148e2.htm?s_cid=mm7148e2_w

What is the current supply of Paxlovid? Do I need to prioritize prescribing based on supply?

- There is currently ample supply of Paxlovid with no anticipated supply constraints in the near future.
- Paxlovid is available by prescription from more than 40,000 locations nationwide.

What are the current recommendations about "rebound" presentation after SARS-CoV-2 infection? Should this impact prescribing?

- Rebound (defined as experiencing recurrence of symptoms and/or SARS-CoV-2 antigen positivity after initial resolution) has been observed not only among patients treated with Paxlovid but **also occurs in patients receiving no treatment and in patients treated with other COVID-19 therapeutics.**
- Recent studies suggest patients experiencing rebound have an extremely **low probability** of developing severe COVID-19. Further studies on this phenomenon are ongoing.
- Additional guidance on the management of patients experiencing rebound is available.

How does a patient obtain Paxlovid if they need it?

- An individual's health care provider remains the first option for assessment and prescribing for patients who have symptoms consistent with COVID-19. Oral antivirals, including Paxlovid, are now available at more than 40,000 locations nationwide.
  - Health care providers should also proactively counsel high-risk patients about the availability of effective therapeutics and discussing a COVID-19 action plan with their patients.
- For individuals who do not have timely access to their own health care provider, there are more than 2,700 Test to Treat sites where patients can get tested, assessed for COVID-19 therapeutic eligibility, and have their prescription filled.
- The FDA also recently authorized pharmacists with access to a patient's health care records to prescribe Paxlovid **under certain conditions**.

Are lab results required before a patient can be prescribed Paxlovid?

- Assessment of renal and hepatic function is important when considering prescribing Paxlovid.
- Licensed physicians and advanced practice providers are not required to perform additional laboratory testing when prescribing Paxlovid. Providers should use clinical judgement to determine if labs are necessary.
- State-licensed pharmacists must have access to a patient's health care records within the past 12 months to assess for renal and hepatic function in order to prescribe Paxlovid.
- Specific information on clinical evaluation considerations to prescribe are in the FDA Fact Sheet for Health Care Providers.

Can patients take Paxlovid if they are taking other medications?

- Drug-drug interactions are important when considering whether to prescribe Paxlovid. Paxlovid may increase the concentration of concomitantly administered medications.
- Despite its potential for drug-drug interactions, many commonly-used medications can be safely co-administered with Paxlovid. The prescriber should perform a thorough medication reconciliation, including over-the-counter medications and supplements, prior to prescribing Paxlovid.
- FDA's Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers includes a helpful table with medications that interact with Paxlovid, and the recommended action for the prescriber.

What are the alternatives to Paxlovid for the patient with mild to moderate COVID-19 illness who cannot take it?

- Veklury is the other preferred treatment for mild to moderate COVID-19. Veklury is given intravenously, once daily for 3 consecutive days.
- Lagevrio (molnupiravir) (oral antiviral) is an alternative treatment when preferred therapies are not clinically appropriate or available.

Where can I get more information?

- Visit us online at aspr.hhs.gov/Paxlovid
- Email any questions to COVID19therapeutics@hhs.gov.
- NIH Therapeutic Management of Non-hospitalized Adults With COVID-19
- FDA Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir and ritonavir)

Paxlovid has not been approved but has been authorized for emergency use by FDA under an EUA, 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.

The emergency use of Paxlovid is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.