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), along with Veklury (remdesivir), are the preferred treatments for eligible adult and pediatric patients with positive results of SARS-CoV-2 testing and who are at risk for progression to severe COVID-19.
- COVID-19 therapeutics should be considered for any SARS-CoV-2 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 patients who meet the following criteria:
  - Test positive for SARS-CoV-2 (with PCR or antigen test, including at-home tests), AND
  - Have symptoms consistent with mild-to-moderate COVID-19 & onset no more than 5 days, AND
  - Have one or more risk factors for severe COVID
- The FDA’s Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers is a useful tool for assessing 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 over 50 years, 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 the 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, United States, and Hong Kong is consistent with benefit in high-risk patients:
  - 67% reduction in hospitalizations and 81% reduction in deaths compared to the untreated for patients over 65
  - 45% reduction in hospitalization and greater reductions for obese or unvaccinated patients among adult patients
  - 75% reduction in death compared to non-users.

References:
1 Ronza Najjar-Debbiny et al. Clinical Infectious Diseases, 2022; cia443, https://doi.org/10.1093/cid/ciac443
3 Carlos K.H. et al. medRxiv 2022.05.19.22275291; doi: https://doi.org/10.1101/2022.05.19.22275291
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 should be considered for any COVID-19 positive patient who meets the eligibility criteria.
- 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 can be found here.

How does a patient obtain Paxlovid if they need it?
- An individual's healthcare provider remains the first option for assessment and prescribing for patients who test positive for SARS-CoV-2. Oral antivirals, including Paxlovid, are now available at more than 40,000 locations nationwide.
  - Healthcare providers should also be proactively counseling 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 healthcare 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 healthcare records to prescribe Paxlovid under certain conditions.

Are lab results required before a patient can be prescribed Paxlovid?
- Patients must test positive for SARS-CoV-2 to be eligible; PCR or antigen tests, including at-home tests, are acceptable.
- 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 healthcare 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 an 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-moderate COVID illness who cannot take it?
- Veklury (remdesivir) is the other preferred treatment for mild-moderate COVID. Veklury is given intravenously, once daily for three consecutive days.
- Lagevrio (molnupiravir) (oral antiviral) and bebtelovimab (monoclonal antibody) are alternative treatments when preferred therapies are not clinically appropriate or available.

Where can I get more information?
- Visit us online at https://aspr.hhs.gov/COVID-19.
- 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)