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From: Humayun Chaudhry <hchaudhry@fsmb.org>
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To: Humayun Chaudhry
Subject: Paxlovid Fact Sheet for Licensees
Attachments: ASPRInfoSheetPaxlovid,Aug2022.pdf

To: All Executive Directors of State and Territorial Medical and Osteopathic Boards

Subject: Paxlovid Fact Sheet for Licensees

Dear Executive Directors,

The White House COVID-19 Response Team is seeking your board's assistance in **sharing the attached Paxlovid information sheet** with all physicians and physician assistants licensed in your state or territory. The information sheet was drafted by the U.S. Department of Health and Human Services (HHS) and includes detailed information about Paxlovid's eligibility and effectiveness. The purpose of sharing this information with licensees is to help them address any questions they or their patients may have about Paxlovid and its effectiveness.

Thank you for considering this request and please let me know if you have any questions.

Hank

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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)**, 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[1], United States[2], and Hong Kong[3] 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[1]
  - **45% reduction in hospitalization and greater reductions for obese or unvaccinated patients** among adult patients[2]
  - **75% reduction in death compared to non-users**[3].

References: [1]Ronza Najjar-Debbiny et al. *Clinical Infectious Diseases*, 2022;, ciac443, https://doi.org/10.1093/cid/ciac443
[2]Scott Dryden-Peterson et al. medRxiv 2022.06.14.22276393; doi: https://doi.org/10.1101/2022.06.14.22276393
[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)