

## 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  $\geq 65$  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](#)<sup>1</sup>, [United States](#)<sup>2</sup> and [Hong Kong](#)<sup>3</sup> 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<sup>1</sup>
  - **45% reduction in hospitalization and greater reductions for obese or unvaccinated patients** among adult patients<sup>2</sup>
  - **75% reduction in death compared to non-users**<sup>3</sup>.

References: <sup>1</sup>Ronza Najjar-Debbiny et al. *Clinical Infectious Diseases*, 2022;, ciac443, <https://doi.org/10.1093/cid/ciac443>

<sup>2</sup>Scott Dryden-Peterson et al. medRxiv 2022.06.14.22276393; doi: <https://doi.org/10.1101/2022.06.14.22276393>

<sup>3</sup>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](mailto:COVID19therapeutics@hhs.gov).
- [NIH Therapeutic Management of Non-hospitalized Adults With COVID-19](#)
- FDA [Fact Sheet for Healthcare Providers for Paxlovid \(nirmatrelvir and ritonavir\)](#)