

Interim DOH Guidance for Use of Paxlovid

Updates (May 11, 2022):

- Reference to FDA updates for health care providers and tool to facilitate appropriate prescribing

About Paxlovid

On December 22, 2021, the FDA provided a [EUA](#) for Paxlovid (nirmatrelvir co-packaged with ritonavir) limited for use for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid consists of two medications, nirmatrelvir and ritonavir, which are co-packaged for oral use. This medicine is authorized for people 12 or older and who weigh at least 40 kilograms. The course of treatment is only indicated for five days and the prescription includes 30 tablets. Nirmatrelvir is a protease inhibitor of SARS-CoV-2, and ritonavir is used to boost levels of the drug. Paxlovid is currently available at select Safeway, Save-on, Haggen's pharmacies, as well as numerous independent pharmacies across Washington. Locations can be found using the following locator: [COVID-19 Therapeutics Locator](#).

The FDA updated the [health care providers' fact sheet](#), creating a list of medications that could lead to drug-drug interactions with Paxlovid. It also released a [checklist](#) to assist providers in prescribing this medication. Noting dosing changes are required for individuals with moderate renal impairment and contraindicated for those with severe renal impairment, the checklist states the *"Prescriber may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of renal impairment. Providers may consider ordering a serum creatinine or calculating the estimated glomerular filtration rate (eGFR) for certain patients after assessment on a case-by-case basis based on history or exam."* It also made note that as risk factors have changed over time, individuals are eligible for Paxlovid even if not fully vaccinated or not boosted and do not require multiple risk factors to be considered "high risk."

Recommendations

The following recommendations should be used to ensure equitable administration for those individuals who might receive the greatest benefit from SARS-CoV-2 antiviral treatment. These recommendations are not prescriptive, but rather should be used in the context of clinical decision-making and other community factors to determine the best treatment option for the specific patient, consistent with current [NIH guidelines](#). The following underlying conditions increase the risk for progression to severe disease:

- ≥ 65 years of age
- 50-65 years of age with chronic medical conditions, especially if not up to date with vaccination
- Cancer
- Cardiovascular disease or hypertension
- Chronic kidney disease
- Chronic lung diseases
- Cystic fibrosis
- Chronic liver diseases
- Complex genetic or metabolic syndromes
- Dementia or other neurological conditions
- Diabetes
- Disabilities
- Downs syndrome
- HIV infection
- Immunosuppression
- Limited access to care or members of communities disproportionately impacted by COVID-19
- Moderately-to-severely immunosuppressed
- Medical-related technological dependence
- Mental health conditions
- Neurodevelopmental disorders
- Overweight and obesity (BMI ≥ 25 kg/m²)
- Physical inactivity
- Pregnancy
- Sickle cell disease or thalassemia
- Severe congenital anomalies
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease
- Tobacco usage, current or former
- Substance use disorders
- Tuberculosis
- Among those individuals who are [up to date](#) with vaccinations, consider prioritizing use to those who are:
 - ≥ 65 years of age
 - Moderately-to-severely immunosuppressed
 - Women who are pregnant, especially those with comorbidities

Authorization of Paxlovid under its [EUA](#) is not limited to the medical conditions or factors listed above. Other medical conditions or factors may also place individual patients at high risk for progression to severe COVID-19. See [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19](#) and [People with Certain Medical Conditions](#).

Though Paxlovid is intended to be used for ambulatory patients with COVID-19, there are

circumstances under which it may be used in hospitalized patients. Per the [EUA](#):

- Paxlovid is authorized for the treatment of patients hospitalized with mild-to-moderate COVID-19, such as patients admitted for monitoring of drug-drug interactions.
- Paxlovid is also authorized for patients hospitalized for conditions other than COVID-19, provided the terms of the authorization are otherwise met, as detailed in the Fact Sheet for Providers.
- Paxlovid is also authorized for patients who require hospitalization due to severe or critical COVID-19 after starting treatment with Paxlovid. These patients should complete the full 5-day treatment course per the healthcare provider's discretion.

Limitations on Authorized Use:

- PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- PAXLOVID is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.
- PAXLOVID is not authorized for use for longer than 5 consecutive days. PAXLOVID may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).

Warnings

- Nirmatrelvir and ritonavir, which comprise Paxlovid, also interact with other medicines, which may lead to serious or life-threatening adverse reactions.
- Liver problems have occurred in patients receiving ritonavir. Therefore, caution should be exercised when administering Paxlovid to patients with pre-existing liver diseases, liver enzyme abnormalities, or hepatitis.
- Paxlovid is not recommended for patients with severe kidney problems, and a different dose is needed for patients with moderate kidney problems.

Because nirmatrelvir is co-administered with ritonavir, there may be a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection. See [Dept of health services HIV guidelines](#) for drug interactions information. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/drug-interactions-between-protease-inhibitors-and-other-drugs?view=full>.

There are limited clinical data available for Paxlovid. Serious and unexpected adverse events may occur that have not been previously reported with Paxlovid use.

Resources

- IDSA guidance: [IDSA Guidelines on the Treatment and Management of Patients with COVID-19 \(idsociety.org\)](#)
- [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers](#)
- [CDC Altered Immunocompetence](#)
- [CDC Yellow Book – Chapter 5 Immunocompromised Travelers](#)
- [Fact Sheet for Patients and Caregivers](#)
- [Fact Sheet for Providers](#)
- [FDA FAQ for Paxlovid](#)
- [People with Certain Medical Conditions](#)

More COVID-19 Information and Resources

- Stay up-to-date on the [current COVID-19 situation in Washington](#), [Governor Inslee's proclamations](#), [symptoms](#), [how it spreads](#), and [how and when people should get tested](#). See our [Frequently Asked Questions](#) for more information.
- The risk of COVID-19 is not connected to race, ethnicity or nationality. [Stigma will not help to fight the illness](#). Share accurate information with others to keep rumors and misinformation from spreading.
- [WA State Department of Health 2019 Novel Coronavirus Outbreak \(COVID-19\)](#)

[WA State Coronavirus Response \(COVID-19\)](#)

- [Find Your Local Health Department or District](#)
- [CDC Coronavirus \(COVID-19\)](#)
- [Stigma Reduction](#) Resources

Have more questions about COVID-19? Call our hotline: **1-800-525-0127**. For interpretative services, **press #** when they answer and **say your language**. (Open from 6 a.m. to 10 p.m.) For questions about your own health, COVID-19 testing, or testing results, please contact your health care provider.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 ([Washington Relay](#)) or email civil.rights@doh.wa.gov.