

## VIRGINIA PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

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*This checklist is intended as an aid to support clinical decision making for prescribers. This form may be completed by the prescribing provider or designee to assist in determining patient eligibility for Paxlovid (nirmatrelvir/ritonavir). This checklist is not a requirement, however, it will help providers understand the currently available evidence, resources, information, emergency use authorization (EUA) requirements and expert opinions. This checklist is subject to change.*

Prescribing Provider Name: \_\_\_\_\_

Date and time of prescription: \_\_\_\_\_

Patient name: \_\_\_\_\_

Patient Date of Birth: \_\_\_\_\_

### **DETERMINING PATIENT ELIGIBILITY**

- Positive SARS-CoV-2 test (Confirmation of a positive home rapid SARS-CoV-2 test result with additional direct SARS-CoV-2 viral testing is not required.)
- Age  $\geq$  12 years of age and weighing at least 40 kg (88lbs)
- Has one or more risk factors for progression to severe COVID-19 (Healthcare providers should consider the benefit-risk for an individual patient.)
- Symptoms consistent with mild to moderate COVID-19
  - Symptoms may include: Cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, sore throat, GI symptoms, diarrhea
- Symptom onset within 5 days
- Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- No known or suspected severe renal impairment (eGFR  $<$  30 mL/min)
  - Note that a dose reduction is required for patients with moderate renal impairment (eGFR  $\geq$ 30- $<$ 60 mL/min); see the Fact Sheet for Healthcare Providers.
  - 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.
- No known or suspected severe hepatic impairment (Child-Pugh Class C)
- No history of clinically significant hypersensitivity reactions [e.g., toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome] to the active ingredients (nirmatrelvir or ritonavir) or other components of the product

### **Assessing Drug Interactions**

#### **NIRMATRELVIR/RITONAVIR (PAXLOVID) DOSING AND COUNSELING**

- Medication should be taken twice daily by mouth for 5 days
- Note: Not authorized for use for longer than 5 consecutive days
- Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID

Patient age 12 years and older AND weight greater than or equal to 40 kg AND eGFR  $\geq$  60 mL/min use **standard dose pack**:

1. **PAXLOVID 300 mg;100 mg Dose Pack**: This packaging configuration should be used for patients with normal renal functions or mild renal impairment (**eGFR\* greater than 60 ml/min**).

Each 300 mg;100 mg Dose Pack includes 5 daily blister cards, each containing a morning and evening dose, with each dose consisting of 300 mg nirmatrelvir (two oval, pink 150 mg tablets) and 100 mg ritonavir (one white or white to off-white film-coated 100 mg tablet uniquely identified by the color, shape, and debossing)<sup>†</sup>.

Patient age 12 years and older AND weight greater than or equal to 40 kg AND eGFR  $\geq$  30 to < 60 mL/min use **renal dose adjusted packaging**:

2. **PAXLOVID 150 mg;100 mg Dose Pack**: This packaging configuration should be used for patients with moderate renal impairment (**eGFR  $\geq$ 30 to <60 mL/min**).

Each 150 mg;100 mg Dose Pack includes 5 daily blister cards, each containing a morning and evening dose, with each dose consisting of 150 mg nirmatrelvir (one oval, pink 150 mg tablet) and 100 mg ritonavir (one white or white to off-white film-coated 100 mg tablet uniquely identified by the color, shape, and debossing)<sup>†</sup>.

PAXLOVID is not recommended (the appropriate dose has not been determined) in patients with severe renal impairment (<30 mL/min).

The following **MUST be documented in the patient's medical record prior to prescribing** nirmatrelvir/ritonavir:

- An **informed consent** process took place, in which the risks, benefits, unknowns of the proposed treatment, and reasonable treatment alternatives were discussed with patient/surrogate and their acceptance or refusal documented.
- That the [Fact Sheet](#) for Patients and Parents/Caregivers was provided to the patient/surrogate
- Patient/surrogate were informed of alternatives to receiving nirmatrelvir/ritonavir
- Patient/surrogate were informed that nirmatrelvir/ritonavir is an unapproved drug authorized for use under the FDA's EUA

If a serious and unexpected adverse event occurs and appears to be associated with the use of molnupiravir, the prescribing health care provider and/or the provider's designee shall complete and submit a MedWatch form within **7 calendar days** from the onset of the event to the FDA using one of the following methods:

- Complete and submit the [report](#) online, or
- Use a postage-paid [Form FDA 3500](#) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form

In addition, please provide a copy of all FDA MedWatch forms to:

- Website [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com)
- Fax number 1-866-635-8337
- Telephone number 1-800-438-1985

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of PAXLOVID.

## Appendix

### Resolving Drug-Drug Interactions

See the [Liverpool COVID-19 Drug Interaction Checker](#) for a more detailed list of drug-drug interactions.

#### **DRUG-DRUG INTERACTIONS**

- HMG-CoA reductase inhibitors (statins)**
  - *If the patient is taking lovastatin or simvastatin, which are contraindicated with PAXLOVID coadministration, PAXLOVID can be given if the statin can be held 12 hours prior to the first dose of PAXLOVID treatment, held during the 5 days of treatment, and restarted 5 days after completing PAXLOVID.*
  - *If the patient is taking atorvastatin or rosuvastatin, consider temporary discontinuation of atorvastatin and rosuvastatin during treatment with PAXLOVID. Atorvastatin and rosuvastatin do not need to be held prior to or after completing PAXLOVID.*
- Hormonal contraceptives containing ethinyl estradiol:** *If the patient is taking a hormonal contraceptive containing ethinyl estradiol, consider an additional non-hormonal method of contraception during the 5 days of PAXLOVID treatment and until one menstrual cycle after stopping PAXLOVID.*
- Medications for HIV-1 Treatment:** *If the patient is taking medications for the treatment of HIV-1 infection, with the exception of maraviroc3, HIV antiretroviral medications can be co-administered with PAXLOVID without dose adjustment, but arranging follow-up by the HIV care provider to monitor for side effects is recommended*