

A template for a standing order is provided below.

[CLINIC NAME]

## Standing Order and Protocol for Initiating Paxlovid Treatment for COVID-19

**Issuing Licensed Health Care  
Provider**

Insert the name of the licensed physician or certified nurse  
practitioner

**Name of Clinic**

Insert the name and address of the participating clinic

**Effective Time Period**

From to

### Signed and Dated Medical Directive/ Non-Patient Specific Standing Order

I, \_\_\_\_\_, a licensed practitioner authorized to prescribe medication in the State of Rhode Island, authorize the clinic staff noted above to dispense Paxlovid medication to individuals who may benefit from this COVID-19 treatment in accordance with the attached protocol.

\_\_\_\_\_  
**Prescriber's Name**

\_\_\_\_\_  
**Prescriber's Signature**

\_\_\_\_\_  
**RI License #**

\_\_\_\_\_  
**Date**

A template for a standing order is provided below.

### **Step One: Screen the Individual to Determine if They Meet the Initial Criteria for Paxlovid**

**Summary:** The U.S. Food and Drug Administration has issued an emergency use authorization for Paxlovid which includes nirmatrelvir, a SARS-CoV-2 main protease inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, for the treatment of **mild-to-moderate** coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and **who are at high risk for progression to severe COVID-19**, including hospitalization or death. Paxlovid is not authorized for: initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19; pre-exposure or post-exposure prophylaxis for prevention of COVID-19; use longer than five (5) consecutive days.

**Source:** <https://www.fda.gov/media/155050/download>

**Has the patient had a positive test for Sars-Cov-2?**

(This can include a home-based antigen test, or a clinic-based PCR or antigen test)

**IF YES → PROCEED TO NEXT QUESTION**

**IF NO → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED.**

**Does the patient have symptoms of COVID-19?**

(This includes fevers, chills, cough, difficulty breathing, fatigue, muscle or body aches, headaches, loss of taste/smell, sore throat, runny nose or congestion, nausea or vomiting, or diarrhea)

[www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html](http://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)

**IF YES → PROCEED TO NEXT QUESTION**

**IF NO → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED.**

**Did symptoms start within five (5) days?**

**IF YES → PROCEED TO NEXT QUESTION**

**IF NO → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED.**

**Does the patient require hospitalization?**

**IF YES → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED;**

**IF NO → PROCEED TO STEP 2**

A template for a standing order is provided below.

**Step Two: Evaluate Patient for Conditions That Increase the Risk for Progression to Severe COVID-19**

**Does the patient have any of the following conditions?**

- Immunocompromised individuals who are not expected to mount an adequate immune response after infection or previous COVID-19 vaccination.
- Age (Strongly consider those >50 years of age and especially if they have other health conditions; prioritize >65 years of age)
- Cardiovascular Disease
- Chronic Renal Disease
- Chronic Lung Disease
- Diabetes
- Obesity (Body mass index >30)

\*Patients with any of the above conditions and who are not up to date with their vaccinations should still be strongly considered for Paxlovid. Those who are up to date with their vaccinations but fall in these groups should also be considered, especially if they are immunocompromised or older age.

**IF YES → PROCEED TO STEP 3**

**IF NO → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED.**

**IMPORTANT:** There are other conditions that *may* increase the risk of severe COVID-19. If the patient has any of the conditions present in **APPENDIX A**, they should be referred to a medical provider for further evaluation. Importantly, pregnancy is considered a risk factor for severe COVID-19. However, there is limited data on Paxlovid in pregnancy and individuals should be referred to a medical provider for further discussion on the risks and benefits.

A template for a standing order is provided below.

**Step Three: Evaluate for Contraindications**

**Does the patient have a known or suspected decrease in their renal function?**

(Paxlovid is not recommended for people with an eGFR<30 mL/min, and needs to be dose adjusted for people with an eGFR  $\geq$ 30 to <60 mL/min)

**IF YES → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED. PATIENT SHOULD BE REFERRED TO A MEDICAL PROVIDER FOR FURTHER EVALUATION**  
**IF NO → PROCEED TO NEXT QUESTION**

**Does the patient have known or suspected severe liver disease?**

(Paxlovid is not recommended for people with Child-Pugh Class C)

**IF YES → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED. PATIENT SHOULD BE REFERRED TO A MEDICAL PROVIDER FOR FURTHER EVALUATION**  
**IF NO → PROCEED TO NEXT QUESTION**

**Does the patient have a history of an allergic/hypersensitivity reaction to either nirmatrelvir or ritonavir)?**

**IF YES → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED. PATIENT SHOULD BE REFERRED TO A MEDICAL PROVIDER FOR FURTHER EVALUATION**  
**IF NO → PROCEED TO STEP 4**

A template for a standing order is provided below.

#### **Step Four: Evaluate for Medication Interactions**

**(Critical Step) Is the patient able to list and confirm all the medications they take including over-the-counter medications and supplements?**

**IF YES → PROCEED TO NEXT QUESTION**

**IF NO → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED. PATIENT SHOULD BE REFERRED TO A MEDICAL PROVIDER FOR FURTHER EVALUATION.**

**(Required Task) Run all medications (including over-the-counter medications and supplements) through: [www.covid19-druginteractions.org](http://www.covid19-druginteractions.org).**

At this site, when running a co-medication against a COVID-19 drug there are four (4) categories of drug interactions results that could be displayed:

- 1) “These drugs should not be co-administered;”
- 2) “Potential clinically significant interaction that is likely to require additional monitoring, alteration of drug dosage or timing of administration;”
- 3) “Potential interaction likely to be of weak intensity. Additional action/monitoring or dosage adjustment is unlikely to be required”; **and**
- 4) “No clinically significant interaction expected.”

**Do all drug interactions result in “no clinically significant interaction expected” (category 4)?**

**IF YES → PROCEED TO STEP 5**

**IF NO → STOP, PAXLOVID SHOULD NOT BE PRESCRIBED. PATIENT SHOULD BE REFERRED TO A MEDICAL PROVIDER FOR FURTHER EVALUATION.**

A template for a standing order is provided below.

**Step Five: Prescribe or Dispense Medication**

Proceed with prescribing or dispensing Paxlovid.

**Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together orally twice daily for 5 days.**

**→ PROCEED TO STEP 6**

A template for a standing order is provided below.

**Step Six: Counseling and Documentation**

- A. Individual will be counseled that side-effects of Paxlovid could include gastrointestinal (i.e., diarrhea), hypertension, taste disturbances, or myalgias. Individuals will be instructed to immediately seek medical attention if any serious side effects occur.
- B. Individuals will be instructed to immediately seek medical attention if symptoms worsen or do not improve on treatment.
- C. Encounter will be documented in the electronic medical record.

A template for a standing order is provided below.

**APPENDIX A: FULL LIST OF CONDITIONS THAT INCREASED THE RISK OF SEVERE COVID-19:** <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>

## Summary of Conditions with Evidence

1. **Higher risk** for severe COVID-19 outcomes is defined as an underlying medical condition or risk factor that has a published meta-analysis or systematic review or complete the [CDC systematic review process](#). The meta-analysis or systematic review demonstrates good or strong evidence, (depending on the quality of the studies in the review or meta-analysis) for an increase in risk for at least one severe COVID-19 outcome.
  - Cancer
  - Cerebrovascular disease
  - Chronic kidney disease\*
  - Chronic lung diseases limited to:
    - Interstitial lung disease
    - Pulmonary embolism
    - Pulmonary hypertension
    - Bronchiectasis
    - COPD (chronic obstructive pulmonary disease)
  - Chronic liver diseases limited to:
    - Cirrhosis
    - Non-alcoholic fatty liver disease
    - Alcoholic liver disease
    - Autoimmune hepatitis
  - Cystic fibrosis
  - Diabetes mellitus, type 1 and type 2\*
  - Disabilities
    - Attention-Deficit/Hyperactivity Disorder (ADHD)
    - Cerebral Palsy
    - Congenital Malformations (Birth Defects)
    - Limitations with self-care or activities of daily living
    - Intellectual and Developmental Disabilities
    - Learning Disabilities
    - Spinal Cord Injuries
    - (For the list of all conditions that were part of the review, [see the module below](#))
  - Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
  - HIV (human immunodeficiency virus)
  - Mental health disorders limited to:
    - Mood disorders, including depression
    - Schizophrenia spectrum disorders

A template for a standing order is provided below.

- Neurologic conditions limited to dementia
  - Obesity (BMI  $\geq 30$  kg/m<sup>2</sup>)\*
  - Primary Immunodeficiencies
  - Pregnancy and recent pregnancy
  - Physical inactivity
  - Smoking, current and former
  - Solid organ or hematopoietic cell transplantation
  - Tuberculosis
  - Use of corticosteroids or other immunosuppressive medications
1. **Suggestive higher risk** for severe COVID-19 outcomes is defined as an underlying medical condition or risk factor that neither has a published meta-analysis or systematic review nor completed the [CDC systematic review process](#). The evidence is supported by mostly cohort, case-control, or cross-sectional studies. (Systematic reviews are available for some conditions for children with underlying conditions.)
- Children with certain underlying conditions
  - Overweight (BMI  $\geq 25$  kg/m<sup>2</sup>, but  $< 30$  kg/m<sup>2</sup>)
  - Sickle cell disease
  - Substance use disorders
  - Thalassemia
2. **Mixed evidence** is defined as an underlying medical condition or risk factor that has a published meta-analysis or systematic review or completing the [CDC systematic review process](#). The meta-analysis or systematic review is inconclusive, either because the aggregated data on the association between an underlying condition and severe COVID-19 outcomes are inconsistent in direction or there are insufficient data (or limited) on the association between an underlying conditions and severe COVID-19 outcomes.
- Alpha 1 antitrypsin deficiency
  - Asthma
  - Bronchopulmonary dysplasia
  - Hepatitis B
  - Hepatitis C
  - Hypertension\*

Footnote: \* indicates underlying conditions for which there is evidence for pregnant and non-pregnant people