CONDITIONS

SARS-CoV-2 Antiviral
TREATMENT OF COVID-19 INFECTION

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe the SARS-CoV-2 Antiviral nirmatrelvir/ritonavir.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized SARS-CoV-2 Antiviral:
    - Patient Intake Form (pg. x-x)
    - Assessment and Treatment Care Pathway (pg. x-x)
    - Prescription Template *optional* (pg. X)
    - Provider Notification (pg. x)

PHARMACIST TRAINING/EDUCATION:

- Pharmacist must be familiar with how to access patient laboratory data to assess renal and hepatic function.
- Review PAXLOVID resources for healthcare providers, available at:
  - Pfizer: https://paxlovid.pfizerpro.com/
  - FDA: PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers
- A minimum of 1 hour of training **is recommended.**
  - CDC Webinar: Diagnostic Testing and Treatment Guidelines for COVID-19 and Influenza
  - APhA CPE: Oral Antivirals for COVID-19: Practical Considerations for Patient Selection, Evaluation for Safe Use, Monitoring and Referral
  - APhA Certificate Program: Pharmacy-Based Test And Treat Certificate Training Program (20 hours)

SARS-CoV-2 Antiviral Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

If you have any of the following, please go directly to the emergency room or have someone call 911.

□ New confusion □ Difficulty breathing □ Pain or pressure in the chest
□ Cannot stay awake □ Gray or blue-colored skin, lips, or nail beds □ Fast heart rate or palpitations
□ If you are on oxygen and have greater oxygen needs

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Theirs, Ze/Hir/Hirs, Other_____Height_____Weight____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? □ Yes □ No Insurance Provider Name _____
Any allergies to medications? □ Yes □ No If yes, please list _____
Which of the following best describes your racial or ethnic identity? Please check **ALL** that apply.
□ Black/African American □ Hispanic or Latino/a/x □ American Indian or Alaska Native □ Asian □ Other
□ Native Hawaiian/Pacific Islander □ Middle Eastern/North African □ White □ Not specified
Are you houseless, or live in a shelter, encampment, or transitional housing? □ Yes □ No

Background Information:

1.	Have you experienced any of the following symptoms? If yes, select all that apply: □ Fever □ Chills □ Cough □ Fatigue □ Headache □ Sore throat or Laryngitis □ Difficulty breathing □ Muscle or body aches □ Loss of taste or smell □ Congestion/head cold □ Runny nose □ Nausea or Vomiting □ Diarrhea □ Loss of appetite □ Light sensitivity If yes, did the symptoms start in the past 5 days?	□ Yes □ No □ Yes □ No
2.	Do you have or have you had any of the following that would qualify you for COVID-19 treatment? Please ask the Pharmacist if you have any questions about this list.	
	A. Age 50 years or older	□ Yes □ No
	B. Asthma	□ Yes □ No
	C. Cancer	□ Yes □ No
	D. Cystic fibrosis	□ Yes □ No
	E. Dementia	□ Yes □ No
	F. Diabetes	□ Yes □ No
	G. Disability (e.g., mental, physicial, emotional)	□ Yes □ No
	H. Heart condition	□ Yes □ No
	I. HIV infection	□ Yes □ No
	J. Immune system problems or medications affecting the immune system	□ Yes □ No
	K. Kidney disease	□ Yes □ No
	a. If yes, are you currently on dialysis?	□ Yes □ No
	L. Liver disease	□ Yes □ No
	M. Lung disease or blood clot in the lung	□ Yes □ No
	N. Mental health condition	□ Yes □ No
	O. Unvaccinated or not up to date on COVID-19 vaccinations	□ Yes □ No
	P. Obesity	□ Yes □ No
	Q. Physically inactive	□ Yes □ No
	R. Pregnancy or recent pregnancy	□ Yes □ No
	S. Smoking, current or former	□ Yes □ No
	T. Transplant of organ or bone marrow	□ Yes □ No
	U. Stroke or brain bleed	□ Yes □ No

SARS-CoV-2 Antiviral Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

	V. Problematic drug or alcohol use……. W. Tuberculosis…… X. Other: _____	□ Yes □ No □ Yes □ No □ Yes □ No
3.	Have you had bloodwork of kidney and liver function that is less than 12 months old? If yes, can you provide it to the Pharmacist now?	□ Yes □ No □ Yes □ No
4.	Do you have any known medication allergies? If yes, list them here: | | | | | | | |	□ Yes □ No
6.	Do you take any medicines, including herbs or supplements? If yes, list them here: | | | | | | | | | | | | | | | |	□ Yes □ No (notify Pharmacist if more space needed)
7.	Do you take any medicines that you do not remember the name of?	□ Yes □ No
8.	Please write the names of all pharmacies you have filled prescriptions with in the last 90 days: Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____	

Signature_____ Date ____/_____/_____

TO BE COMPLETED BY PHARMACIST:

1. SARS-CoV2 test (if intern or pharmacy technician performed the test they may fill in #1)
   a. Manufacturer: _____ Lot #:_____ Expiration Date: ___/___/_____
   b. Test performed by: _____ Date: ___/___/_____ Time: _____:_____ AM / PM (circle one)
   c. Result: □ Reactive □ Non-Reactive □ Indeterminate
2. Weight _____ lbs.
   a. *If applicable* to verify obesity as only risk factor: Height __ ft. ___ in., BMI _____
3. Renal function:
   a. Provider verified eGFR is ≥60 mL/min *or* ≥30 to <60 mL/min *or* <30 mL/min (circle one).
      Provider name (phone):_____ **-or-**
   b. SCr:_____ mg/dL (date of lab:___/___/___). eGFR using CKD-EPI formula:_____ mL/min
4. Hepatic function:
   a. Provider-verified patient has: No Cirrhosis *or* Child-Pugh Class A *or* Class B *or* Class C (circle one)
      Provider name/phone:_____ **-or-**
   b. Total Bilirubin_____ mg/dL (date of lab:___/___/___), Albumin:_____ g/dL (date of lab:___/___/___),
      INR or Prothrombin Time (sec):_____ (date of lab:___/___/___).
      Child-Pugh score:_____ (6 points added for missing ascites and encephalopathy information)
      Estimated Child-Pugh: Class A: 5-6 points *or* Class B: 7-9 points *or* Class C: 10-15 points (circle one)

IF SARS-CoV-2 ANTIVIRAL WAS PRESCRIBED, COMPLETE THE FOLLOWING:

1. Dose (check one):
   □ Nirmatrelvir 300 mg (two 150 mg tablets) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days
   □ Nirmatrelvir 150 mg (one 150 mg tablet) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days
2. Healthcare Provider (if known) contacted/notified of therapy: □ Yes Date ____/_____/_____ □ Not Applicable

RPH Signature_____Date ____/_____/_____

Standardized Assessment and Treatment Care Pathway
SARS-CoV-2 Antiviral

1) Assessment Screen (Self-screening Patient Intake Form, REALD demographics and pharmacist assessment)

a. Age < 18 years → **Refer to healthcare provider**
b. Clinical Factors listed below: → **Refer immediately to local Emergency Department or call 911**
   If the Pharmacist observes or the patient reports:
   □ New confusion □ Difficulty breathing □ Cannot stay awake
   □ Pain or pressure in the chest □ Gray or blue-colored skin, lips, or nail beds
   □ Fast heart rate or palpitations □ If patient is on oxygen and has greater oxygen needs

If referral criteria not met, *proceed to Step 2*.

2) Treatment Screen (Self-screening Patient Intake Form #1-2)

a. Positive CLIA-waived, EUA-authorized, FDA-cleared, or FDA-approved SARS-CoV-2 molecular or antigen test completed by Pharmacist (or Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician)* today?

   NOTE: Results that are indeterminate or inconclusive results can suggest the presence of SARS-CoV-2 in quantities insufficient for the molecular or antigen test to be positive. It is recommended to collect a new specimen and retest. If the results are still indeterminate or inconclusive, the patient should be referred to their healthcare provider for further evaluation.

   *Per 2024 SB 1506: A Pharmacist may delegate to an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician who is under the Pharmacist's supervision the administrative and technical tasks of performing a SARS-CoV-2 molecular or antigen test.

b. Onset of mild to moderate COVID-19 symptoms within past 5 days?

   NOTE: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea, vomiting; or diarrhea

If YES to *BOTH* Steps 2a **AND** 2b, *proceed to Step 3*.

3) Risk of Progression to Severe COVID-19 Screen (Self-screening Patient Intake Form #3, REALD demographics)

a. Did the patient attest to at least one risk factor in #3 on the Self-screening Patient Intake Form, which places an individual at high risk of progression to severe COVID-19?

   NOTE: Pharmacist must obtain or calculate BMI to verify obesity if #3.P. is the *only* risk factor checked "Yes" on #3 of the Self-screening Patient Intake Form. A BMI ≥30 is a risk factor for severe disease.

b. Does the patient identify as Black, African American, Hispanic, Latino/a/x, American Indian/Alaska Native, Asian, Asian American, or Pacific Islander?

NOTE: People of racial and ethnic minority groups are most harmed by health inequities due to racial, ethnic and socioeconomic disparities. These health inequities place these individuals at high risk of progression to severe COVID-19.

c. Is the patient houseless or live in a shelter, encampment or transitional housing, which places an individual at high risk of progression to severe COVID-19?

NOTE: There is increased transmission of virus in indoor and outdoor congregate settings that do not provide protection from the environment, adequate access to hygiene and sanitation facilities, or connection to services and health care. These settings include those where people who are houseless, are sleeping outdoors or in encampments.

If YES to *EITHER* Step 3a, 3b, **OR** 3c, *proceed to Step 4*; otherwise, PAXLOVID is not indicated under this protocol.

4) Renal Function Assessment Screen

a. Is the patient currently on dialysis as reported on the Self-Screening Patient Intake Form Question #3.K.a.?

b. Did the pharmacist verify an eGFR ≥30 mL/min after consultation with a healthcare provider who is in an established patient-provider relationship with the individual patient?

c. Did the pharmacist obtain a SCr level that is less than 12 months old and calculate an eGFR ≥30 mL/min using an online calculator based on the 2021 CKD-EPI equation?

Note: Patient reporting of renal function is not adequate for utilization of this protocol.

If YES to Step 4a, PAXLOVID is contraindicated → Advise patient to seek care from medical provider for further evaluation.
If YES to *EITHER* Step 4b **OR** 4c, *proceed to Step 5*; otherwise, PAXLOVID is not indicated under this protocol → Advise patient to seek care from medical provider for further evaluation.

5) Hepatic Function Assessment Screen

a. Did the pharmacist verify the patient does not have Child-Pugh Class C liver disease (severe, decompensated) after consultation with a healthcare provider who is in an established patient-provider relationship with the individual patient?

b. Did the pharmacist obtain a total bilirubin, albumin and INR/prothrombin time that is less than 12 months old and estimate the Child-Pugh score to be <10 points (no liver cirrhosis, or Child-Pugh Class A or B) using an online calculator?

If provider cannot be consulted to verify hepatic function, pharmacist may calculate the Child-Pugh score using 3 points for missing ascites data and 3 points for missing encephalopathy data (adds 3 points for each missing data) for most conservative estimate.

Note: Patient reporting of liver function is not adequate for utilization of this protocol.

Standardized Assessment and Treatment Care Pathway
SARS-CoV-2 Antiviral

If YES to *EITHER* Step 5a **OR** 5b, *proceed to Step* 6; otherwise, PAXLOVID is not indicated under this protocol → Advise patient to seek care from medical provider for further evaluation.

6) Allergy Screen (Self-screening Patient Intake Form #5)

Does the patient have a known allergy/hypersensitivity to any ingredient of PAXLOVID?

If NO known allergy, *proceed to Step 7*; otherwise, PAXLOVID is contraindicated → Advise patient to seek care from medical provider for further evaluation.

7) Assessment of Drug-Drug Interactions (Self-screening Patient Intake Form #6-8)

a. Did the pharmacist obtain a comprehensive list of current medications and supplements (prescribed and non-prescribed):
   i. Through access to health records or pharmacy records less than 12 months old **-or-**
   ii. In consultation with a healthcare provider in an established patient-provider relationship with the patient **-or-**
   iii. Through patient reporting

b. After review of the medications, did the pharmacist identify potential serious drug interactions with PAXLOVID using product labeling or other drug interaction tool?

If YES to Step 7a **AND** *NO* to Step 7b, *proceed to Step 8*; otherwise, PAXLOVID is not indicated under this protocol → Advise patient to seek care from medical provider for further evaluation.

8) Prescribe PAXLOVID

a. If eGFR ≥60 mL/min: nirmatrelvir 300 mg (two 150 mg tablets) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days, or
b. If eGFR ≥30 to <60 mL/min: nirmatrelvir 150 mg (one 150 mg tablet) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days.

9) Notify primary care provider (if known) within 5 days of receipt of therapy

SARS-CoV-2 Antiviral Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

☐ Drug: Paxlovid™ (nirmatrelvir 300 mg/ ritonavir 100 mg)

- Sig: Take two tablets of nirmatrelvir 150 mg (300 mg) and one tablet of ritonavir 100 mg twice daily for 5 days
- Quantity: #30
- Refills: none

☐ Drug: Paxlovid™ (renal dosing - nirmatrelvir 150 mg/ ritonavir 100 mg)

- Sig: Take one tablet of nirmatrelvir 150 mg and one tablet of ritonavir 100 mg twice daily for 5 days
- Quantity: #20
- Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

Provider Notification
SARS-CoV-2 Antiviral

Pharmacy Name:_____ Pharmacist Name: _____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) was:

Prescribed the SARS-CoV2 Antiviral, Paxlovid™, at our Pharmacy noted above on ___/___/_____. The prescription issued and dispensed consisted of (check one):

- ☐ Paxlovid™ (nirmatrelvir 300 mg and ritonavir 100 mg)
  - Sig: Take two tablets of nirmatrelvir 150 mg (300 mg) and one tablet of ritonavir 100 mg twice daily for 5 days, #30, no refills
- ☐ Paxlovid™ (renal dosing- nirmatrelvir 150 mg and ritonavir 100 mg)
  - Sig: Take one tablet of nirmatrelvir 150 mg and one tablet of ritonavir 100 mg twice daily for 5 days, #20, no refills

Your patient was informed that an office visit with you or another provider on your team is recommended after finishing the course of treatment.

If you have further questions, please contact the prescribing pharmacy.

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

Attention Pharmacy: This is a template document. Please feel free to customize it to your pharmacy, however you must retain all elements set forth by this template. The information may be transmitted electronically.