

## COVID-19 Vaccination and Therapeutics in PALTC Toolkit: Resources for Clinicians

September 20, 2023

#### Abstract

During a meeting with members of the White House COVID-19 Response Team on October 17, 2022, leaders from healthcare associations across the country were asked to educate their members and stakeholders about the importance, effectiveness and accessibility of the COVID-19 vaccines and the therapeutics available to treat those diagnosed with COVID-19. AMDA-The Society for Post-Acute and Long-Term Care Medicine partnered with the American Society of Consultant Pharmacists, the Gerontological Advance Practice Nurses Association, the American Association of Nurse Practitioners, and the American Academy of Physician Associates to create this toolkit for clinicians working in post-acute and long-term care settings, treating the most vulnerable of our population.

## COVID-19 Vaccination and Therapeutics Toolkit: Resources for Clinicians

#### 1. Included Content:

- Recommendations for COVID-19 Vaccine for 2023-2024 Respiratory Virus Season
- Myths and Facts about Paxlovid
- Paxlovid Standing Order Template (Nebraska Antimicrobial Stewardship Assessment and Promotion Program)
- Paxlovid Treatment Order Form(Nebraska Antimicrobial Stewardship Assessment and Promotion Program)
- Pharmacist Ordering Flowchart (ASCP)
- Paxlovid Contraindications Shortlist
- Fact sheet on Paxlovid for patients and families
- 10 Things to Know about COVID-19 Antiviral Pills, from Good Rx
- Role of the Medical Director in Effective Prevention & Treatment of COVID-19

#### 2. Additional Resources on Vaccinations:

- CDC's Bridge Access Program for no-cost vaccines: https://www.cdc.gov/vaccines/programs/bridge/
- Training on updated NHSN reporting: <u>https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html#anchor\_79535</u>
- Centers for Disease Control and Prevention Stay Up To Date with COVID-19 Vaccines: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html</u>
- Vaccine education materials from the Department of Health and Human Services as part of the "We Can Do This" initiative: <u>https://wecandothis.hhs.gov/.</u>
- Building Trust in LTC: A Strategy to Improve Vaccine Uptake, Patient Safety, and Staff Wellbeing: <u>https://www.ahcancal.org/education/Pages/Building-Trust.aspx</u>

#### 3. Additional Resources in Therapeutics:

- Side-by-side Overview of Therapeutics Authorized or Approved for the Treatment of Mild to Moderate COVID-19:
   https://www.bbs.gov/COVID-19/Therapeutics/Decuments/side\_by\_side\_overview.pdf
  - https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/side-by-side-overview.pdf
- Nebraska Antimicrobial Stewardship Assessment and Promotion Program: <u>https://asap.nebraskamed.com/covid-19-treatment/paxlovid/</u>
- ASPR: The Administration for Strategic Preparedness & Response: <u>https://aspr.hhs.gov/COVID-19/treatments</u>
- Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers: <u>https://www.fda.gov/media/158165/download</u>

#### 4. Co-Management of COVID-19 and Influenza:

• Testing and Management Considerations for Nursing Home Residents with Acute Respiratory Illness Symptoms when SARS-CoV-2 and Influenza Viruses are Co-circulating: <u>https://www.cdc.gov/flu/professionals/diagnosis/testing-management-considerations-</u> <u>nursinghomes.htm</u>

## Recommendations for the 2023-2024 UpdatedCOVID-19 Vaccine

#### **Dosing Guidelines**

- Everyone ages 5 years and older is recommended to receive 1 dose of updated (2023-2024 Formula) mRNA COVID-19 vaccine.
- People who are moderately or severely immunocompromised:
  - Initial vaccination: should receive a 3-dose series of updated (2023-2024 Formula) Moderna or updated (2023-2024 Formula) Pfizer-BioNTech COVID-19 vaccine
  - Received previous mRNA doses: need 1 or 2 does of updated (2023-2024 Formula) Moderna or updated (2023-2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
  - May receive 1 or more additional updated (2023-2024 Formula) mRNA COVID-19 vaccine doses
- If you have had a recent COVID-19 infection, you should wait 3 months before getting the vaccine.
  - You should wait at least 2 months from your last COVID-19 vaccine before getting the new 2023-2024 COVID-19 vaccine.
- Bivalent mRNA COVID-19 vaccines are no longer recommended in the United States.
- **Coadministration:** Data has shown that coadministration of the COVID-19 vaccine with the flu vaccine is both safe and effective.<sup>1</sup>





\*For information about administration intervals, people who transition from age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

Image source<sup>:</sup> Webinar Tuesday, September 19, 2023 - Preparing for the Upcoming Respiratory Virus Season: Recommendations for Influenza, COVID-19, and RSV Vaccines for Older Adults (cdc.gov)

<sup>1</sup>Gonen T, Barda N, Asraf K, et al. Immunogenicity and Reactogenicity of Coadministration of COVID-19 and Influenza Vaccines. *JAMA Netw Open*. 2023;6(9):e2332813. doi:10.1001/jamanetworkopen.2023.32813.

For more information: <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u>

## Myths and Facts About Paxlovid

Adapted from ASPR Fact Sheet: https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Paxlovid/Documents/paxlovid-information-sheet.pdf

1. MYTH: Paxlovid is not "worth the trouble" as most patients won't see significant benefit.

**FACT:** The benefit of a 5-day treatment course of Paxlovid was demonstrated in a clinical trial that showed that among non-hospitalized, unvaccinated patients at high risk of progression to severe disease, <u>treatment with Paxlovid reduced the risk of hospitalization or death by 88%</u>. Observational data, including vaccinated patients, from Israel, United States, and Hong Kong is consistent with benefit in high-risk patients:

- 67% reduction in hospitalizations and 81% reduction in deaths compared to the untreated for patients over 651
- 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>

A recent study (Paxlovid reduces risk of Long COVID (va.gov)), which included more than 56,000 Veterans with a positive SARS-CoV-2 test, showed that those given nirmatrelvir (Paxlovid) in the first 5 days of a COVID-19 infection had a 25% decreased risk of developing 10 of 12 different Long COVID conditions studied — including heart disease, blood disorders, fatigue, liver disease, kidney disease, muscle pain, neurocognitive impairment and shortness of breath.<sup>4</sup>

<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: <u>https://doi.org/10.1101/2022.06.14.22276393</u> <sup>3</sup>Carlos K.H. et al. medRxiv 2022.05.19.22275291; doi: <u>https://doi.org/10.1101/2022.05.19.22275291</u> <sup>4</sup>Yan Xie, Taeyoung Choi, Ziyad Al-Aly medRxiv 2022.11.03.22281783; doi: https://doi.org/10.1101/2022.11.03.22281783

2. MYTH: Paxlovid is difficult to access for facilities in rural areas.

**FACT:** There is currently ample supply of Paxlovid with no anticipated supply constraints. Paxlovid should be considered for any COVID-19 positive patient who meets the eligibility criteria. Work with your long-term care pharmacy partner to develop a process for accessing Paxlovid so you are prepared to test and treat immediately.

3. **MYTH:** "Rebound" COVID is common in those who take Paxlovid, so patients would rather take their chances and not risk testing positive again and having to isolate a second time.

**FACT:** 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 <u>but also occurs in patients receiving no treatment</u> or those treated with other COVID-19 therapeutics. Recent studies suggest patients experiencing rebound have an extremely low probability of developing severe COVID-19.

4. **MYTH:** Paxlovid has many drug-drug interactions, which makes it very difficult to prescribe to many patients in long-term care, who are on multiple medications.

**FACT:** 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 <u>Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers</u> includes a helpful table with medications that interact with Paxlovid, and the recommended action for the prescriber.

5. **MYTH:** Since Paxlovid cannot be crushed, patients with dysphasia do not have any other antiviral treatment options.

**FACT:** Veklury (remdesivir) is the other preferred treatment for mild-moderate COVID. Veklury is given intravenously, once daily for three consecutive days. In addition, under the emergency use authorization, monupiravir (Lagevrio) capsules may be opened and administered via Nasogastric (NG) or Orogastric (OG) Tube (12F or Larger).

6. **MYTH:** Clinicians should wait until a patient is experiencing severe symptoms before treating with Paxlovid.

**FACT:** Clinicians should consider treatment based on clinical conditions and not symptom severity. For older patients with frailty, waiting for symptoms to become severe may miss the window for treatment or miss the opportunity to prevent progression towards severe symptoms.

Paxlovid (nirmatrelvir; ritonavir) Standing Order

To be used as first-line therapy for COVID-19 unless not clinically indicated or refused by patient/family

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

Facility:	
Date of symptom	Date of positive
onset:	SARS-CoV-2 test:
CHANGE IN BASELINE OXYGEN REQUIREMEN	TS?
🗆 No 🛛 Yes (Explain):	

#### Diagnosis: \_\_\_\_\_

Paxlovid is available 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 40kg):

- With positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing
- Within 5 days of symptom onset and as soon as possible after diagnosis of COVID-19 ٠
- Who are at high-risk for progression to severe COVID-19 including hospitalization or death (Figure 1) ٠

#### Figure 1: High-Risk Criteria (must meet at least 1)

Older age (for example, age ≥50 years of age)
Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI
≥85th percentile for their age and gender based on CDC growth charts)
Pregnancy
Chronic kidney disease
Diabetes
Immunosuppressive disease or immunosuppressive treatment
Cardiovascular disease (including congenital heart disease) or hypertension
Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma
[moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary
hypertension)
Sickle cell disease
Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that
confer medical complexity (for example, genetic or metabolic syndromes and severe
congenital anomalies)
Having a medical-related technological dependence (for example, tracheostomy,
gastrostomy, or positive pressure ventilation (not related to COVID 19))
Other:

Figure 2

Severity of Criteria			
Illness			
Asymptomatic or Presymptomatic	Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test or an antigen test), but who have no symptoms that are consistent with COVID-19.		
Mild Illness	Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.		
Moderate Illness	Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO2) ≥94% on room air at sea level.		
Severe Illness	Individuals who have SpO2 <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, respiratory frequency >30 breaths per minute, or lung infiltrates >50%		

Source: COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed 18 Nov 2020.

#### Paxlovid (nirmatrelvir; ritonavir) Standing Order

PATIENT ID STICKER

To be used as first-line therapy for COVID-19 unless not clinically indicated or refused by patient/family

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

Facility:

As the healthcare provider, you MUST communicate to your patient or parent/caregiver information consistent with the "Fact Sheet for Patients and Parents/Caregivers" prior to the patient receiving Paxlovid AND MUST document in the patient's medical record. This order form certifies that:

- I have confirmed that this patient meets criteria for emergency use of Paxlovid. ٠
- I have reviewed with the patient/current medical decision maker information consistent with that provided by the FDA's Emergency Use ٠ Authorization (EUA) "Fact Sheet for Patients and Parents/Caregivers" for Paxlovid and have provided a copy of this fact sheet.
- Communication to the patient/caregiver included:
  - o FDA has authorized the emergency use of Paxlovid for the treatment of mild to moderate confirmed COVID-19 who are at high risk of progressing to severe COVID-19 including hospitalization or death.
  - The patient or parent/caregiver has the option to accept or refuse Paxlovid. 0
  - The significant known and potential risks and benefits of Paxlovid, and the extent to which such risks and benefits are unknown. 0
  - 0 Information on available alternative treatments and the risks and benefits of those alternatives including clinical trials.
  - 0 Patients treated with Paxlovid should continue to self-isolate and use infection control measures according to CDC guidelines.
- I have discussed that this medication is an FDA unapproved drug authorized for emergency use only for patients with laboratory confirmed COVID-19. I have communicated the risks, benefits, and alternatives to use as outlined in the fact sheet and have offered the opportunity for questions.
- The patient/current medical decision maker elected to proceed with treatment and has been Informed to report all adverse reactions to a healthcare provider<sup>1</sup>

<sup>1</sup>The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to Paxlovid treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "Paxlovid use for COVID-19 under Emergency Use Authorization (EUA)" in the description section of the report. Complete and submit the report here: www.fda.gov/medwatch/report.htm

#### Attestation:

#### The provider must review the following:

□ No significant drug-drug interactions exist with Paxlovid for any of the medications patient is currently receiving. Drug-drug interactions can be assessed at https://www.covid19-druginteractions.org/

Patient doesn't have severe renal impairment (eGFR<30 mL/min)</p>

Patient doesn't have severe liver impairment (Child-Pugh Class C)

#### Order:

Nirmatrelvir must be co-administered with ritonavir. Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. Administer orally with or without food. Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.

Dose reduction for moderate renal impairment (eGFR  $\geq$  30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.

Medical Director signature:	Date:
Medical Director name (Please print):	

Rev. 4/13/22

Paxlovid (nirmatrelvir; ritonavir) Treatment Order Form PATIENT ID

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

Facility:

Date of symptom		Date of positive	
onset:		SARS-CoV-2 test:	
CHANGE IN BASELINE OXYGEN REQUIREMENTS?			
🗆 No 🗆 Yes (Explain):			

#### Diagnosis:

Paxlovid is available 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 40kg):

- With positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing
- Within 5 days of symptom onset and as soon as possible after diagnosis of COVID-19
- Who are at high-risk for progression to severe COVID-19 including hospitalization or death (Figure 1)

#### Figure 1: High-Risk Criteria (must meet at least 1)

☐ Older age (for example, age ≥50 years of age)	
Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI	
⊇85th percentile for their age and gender based on CDC growth charts)	
Pregnancy	
Chronic kidney disease	
Diabetes	
Immunosuppressive disease or immunosuppressive treatment	
Cardiovascular disease (including congenital heart disease) or hypertension	
Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma	
[moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary	
hypertension)	
Sickle cell disease	
Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that	
confer medical complexity (for example, genetic or metabolic syndromes and severe	
congenital anomalies)	
Having a medical-related technological dependence (for example, tracheostomy,	
gastrostomy, or positive pressure ventilation (not related to COVID 19))	
Other:	

#### Figure 2

Severity of Illness	Criteria
Asymptomatic or Presymptomatic	Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test or an antigen test), but who have no symptoms that are consistent with COVID-19.
Mild Illness	Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.
Moderate Illness	Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO2) ≥94% on room air at sea level.
Severe Illness	Individuals who have SpO2 <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, respiratory frequency >30 breaths per minute, or lung infiltrates >50%

Rev 11/11/2022

Paxlovid (nirmatrelvir; ritonavir) Treatment Order Form PATIENT ID

Patient Name: Date of Birth:

Facility:

Source: COVID-39 Treatment: Guidelines Parel. Coronavirus Disease 2029 [CDVID-39] Treatment Guidelines. National Institutes of Health. Available at https://www.covid28treatmentguidelines.nihgov/. Accessed 28 Nov 2020.

As the healthcare provider, you MUST communicate to your patient or parent/caregiver information consistent with the "Fact Sheet for Patients and Parents/Caregivers" prior to the patient receiving Paxlovid AND MUST document in the patient's medical record. This order form certifies that:

- I have confirmed that this patient meets criteria for emergency use of Paxlovid.
- I have reviewed with the patient/current medical decision maker information consistent with that provided by the FDA's Emergency Use Authorization (EUA) "Fact Sheet for Patients and Parents/Caregivers" for Paxlovid and have provided a copy of this fact sheet.
- Communication to the patient/caregiver included:
  - o FDA has authorized the emergency use of Paxlovid for the treatment of mild to moderate confirmed COVID-19 who are at high risk of progressing to severe COVID-19 including hospitalization or death.
  - The patient or parent/caregiver has the option to accept or refuse Paxlovid. 0
  - The significant known and potential risks and benefits of Paxlovid, and the extent to which such risks and benefits are unknown. 0
  - Information on available alternative treatments and the risks and benefits of those alternatives including clinical trials. 0
  - 0 Patients treated with Paxlovid should continue to self-isolate and use infection control measures according to CDC guidelines.
- I have discussed that this medication is an FDA unapproved drug authorized for emergency use only for patients with laboratory confirmed COVID-19. I have communicated the risks, benefits, and alternatives to use as outlined in the fact sheet and have offered the opportunity for questions.
- The patient/current medical decision maker elected to proceed with treatment and has been Informed to report all adverse reactions to a healthcare provider<sup>1</sup>

<sup>1</sup>The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to Paxlovid treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "Paxlovid use for COVID-19 under Emergency Use Authorization (EUA)" in the description section of the report. Complete and submit the report here: www.fda.gov/medwatch/report.htm

#### Attestation:

#### The provider has reviewed the following:

□ No significant drug-drug interactions exist with Paxlovid for any of the <u>medications</u> patient is currently receiving Drug-drug interactions can be assessed at https://www.covid19-druginteractions.org/

Patient doesn't have severe renal impairment (eGFR<30 mL/min)</p>

Patient doesn't have severe liver impairment (Child-Pugh Class C)

#### Order:

Nirmatrelvir must be co-administered with ritonavir. Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. Administer orally with or without food. Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.

□ Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet)</p> with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.

Prescriber signature: \_\_\_\_\_ Date: \_\_\_\_\_

Prescriber name (Please print):

Rev 1/17/2022

## **Pharmacist Ordering Flowchart for Paxlovid**

## PATIENT TESTS POSITIVE FOR COVID-19

#### REVIEW PATIENTS MEDICAL HISTORY AND MEDICATION LISTS

Specific areas of concern: renal function, hepatic function and drug-drug interactions

**Mechanism to achieve:** printed or electronic health record & blood work (within the last 12 months), consultation with patient's healthcare provider, and medication list, including over-the-counter



- 2. There is sufficient information to assess for a potential drug interaction.
- No modification of other medications is needed due to a potential drug interactions with Paxlovid.
- Paxlovid is an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers and recommended potential drug interactions monitoring is feasible.



Health Care Provider Fact Sheet: www.fda.gov/media/155050/download



## **PAXLOVID Contraindications Shortlist**

Ritonavir-boosted nirmatrelvir (PAXLOVID) has significant drug-drug interactions, primarily due to the ritonavir component of the combination. Before prescribing ritonavir-boosted nirmatrelvir, clinicians should carefully review the patient's concomitant medications, including over-the-counter medications, herbal supplements, and recreational drugs, to evaluate potential drug-drug interactions.

### **Contraindications to PAXLOVID Administration**

- History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components.
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions.
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.

## **Contraindicated Concomitant Medications**

For some of these medications, management strategies are NOT possible or feasible and require an alternative COVID-19 therapy. In some instances, temporarily withholding the concomitant medication or using an alternative to the concomitant medication is clinically appropriate. Read more <u>here</u>. (See list on next page.)

#### Prescribe Alternative COVID-19 Therapy

#### Temporarily Withhold Concomitant Medication, if Clinically Appropriate

#### Anticonvulsants

- Carbamazepine
- Phenobarbital
- Phenytoin
- Primidone

#### Anti-infectives

- Glecaprevir/ pibrentasvir
- Rifampin
- Rifapentine

#### Antipsychotics

- Lurasidone
- Pimozide

## **HMG-CoA** reductase

#### inhibitors

- Atorvastatin
- Lomitapide
- Lovastatin
- Rosuvastatin
- Simvastatin •

#### **Immunosuppressants**

- Everolimus
- Sirolimus •
- Tacrolimus
- Voclosporin

#### Cardiovascular

- Aliskiren
- Amiodarone •
- ٠ Clopidogrel
- Disopyramide •
- Dofetilide ٠
- Dronedarone •
- **Eplerenone** •
- Flecainide •
- Ivabradine •
- Propafenone •
- Quinidine
- Ranolazine
- Ticagrelor
- Vorapaxar
- Neuropsychiatric
  - Clozapine •
  - Lurasidone ٠
  - Midazolam (oral) •
  - Pimozide

#### **Opioid antagonists**

#### Naloxegol • **Pulmonary hypertension**

#### Sildenafil •

- Tadalafil
- Vardenafil

#### Miscellaneous

- Alfuzosin
- Avanafil •
- Bosentan •
- Colchicine
- Eletriptan
- **Ergot derivatives** •
- Erythromycin
- Finerenone
- Flibanserin
- Lumacaftor/ivacaftor •
- Rivaroxaban
- Salmeterol
- Silodosin
- St. John's wort •
- **Suvorexant** •
- Tolvaptan •
- Triazolam •
- Ubrogepant •
- Voclosporin •

- Limitations of 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 post-exposure prophylaxis for prevention of COVID-19.
- PAXLOVID is not authorized for use for longer than 5 consecutive days. ٠

## Additional Resources

COVID-19 Treatment Guidelines: PAXLOVID (NIH)

PAXLOVID Fact Sheet for Healthcare Providers

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

# 10 Things to Know About COVID-19 Antiviral Pills



## Paxlovid Fact Sheet for Patients, Residents, and their Caregivers

Your healthcare provider believes you would benefit from taking Paxlovid for the treatment of mild-tomoderate coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. This Fact Sheet contains information to help you understand Paxlovid.

#### What Is Paxlovid and why is my practitioner recommending I take it?

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to make Paxlovid available during the COVID-19 pandemic. Paxlovid is an investigational medicine used to treat mild-to-moderate COVID-19 in adults and children 12 years of age and older who weigh at least 88 pounds AND have a positive SARS-CoV-2 test, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

#### What should I tell my healthcare provider before I take Paxlovid?

Tell your healthcare provider if you:

- Have any allergies
- Have liver or kidney disease
- Are pregnant or plan to become pregnant
- Have any serious illnesses

**Tell your healthcare provider about all the medicines you take**, including prescription and overthe-counter medicines, vitamins, and herbal supplements.

- Some medicines may interact with Paxlovid and may cause serious side effects.
- Tell your healthcare provider if you are taking combined hormonal contraceptive.

#### How do I take Paxlovid?

Paxlovid consists of 2 medicines: nirmatrelvir and ritonavir.

- Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth 2 times each day (in the morning and in the evening) for 5 days. For each dose, take all 3 tablets at the same time.
- If you have kidney disease, talk to your healthcare provider. You may need a different dose.
- Swallow the tablets whole. Do not chew, break, or crush the tablets.
- Take Paxlovid with or without food.
- Do not stop taking Paxlovid without talking to your healthcare provider, even if you feel better.

If you miss a dose of Paxlovid within 8 hours of the time it is usually taken, take it as soon as you remember. If you miss a dose by more than 8 hours, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of Paxlovid at the same time.



## Role of the Medical Director in Effective Prevention and Treatment of COVID-19

The Medical Director's role and responsibility is to be a leader in the prevention and treatment of COVID-19 in the PALTC facilities they serve, and to oversee the development of effective and practical policies toward that end. As medical directors work to standardize the prevention and treatment of COVID-19 across PALTC settings, the Society recommends the following steps/strategies:

#### 1. COVID-19 Vaccination

- Medical director should support policy for timely vaccination against respiratory illnesses including the updated COVID booster and influenza vaccine. This could include:
  - Coordination and consultation between providers and pharmacists in caring for and immunizing/treating patients
  - Including vaccination consents in admission documents
  - empowering key facility staff through vaccine education thus enabling them to effectively counsel residents, family members and peers see the AMDA COVID-19 Bivalent fact sheet & Alliant's Myths and Facts about the Bivalent Vaccine sheet)
  - Ensuring adequate supplies of vaccines and frequency of clinics in collaboration with consultant pharmacists
  - Ensuring staff education through events like town halls/in-services/educational materials in collaboration with nursing and facility leadership
  - Encouraging open communication of concerns about the vaccine and creating a safe and supportive environment to build trust
  - Ensuring that the assigned infection preventionist/consultant pharmacist is tracking the vaccination of the residents and staff and appropriately documenting in the NHSN and other state vaccine databases
  - o Including the vaccination rates in the QAPI/antibiotic stewardship data
  - Promoting coadministration of influenza and COVID vaccine to mitigate risk of preventable respiratory illnesses

#### 2. COVID-19 Prevention

- PPE
  - Review facility policy and procedure
    - Know when N95 or KN95 masks must be used versus surgical masks, and when should face masks/goggles be worn
    - Visitor PPE use and education
    - Resident PPE use
  - Review facility education regarding donning and doffing PPE
  - Review fit testing for N95 (initial, annual and PRN fit testing)
- Infection control precautions

- Review policy and procedure for infection control
- Review signage for quarantine and isolation
- Review PPE storage and discard
- Review hand sanitizing and washing access and standards
- Review environmental measures such as ensuring proper ventilation, closing doors, cleaning/sanitizing equipment and frequently touched surfaces, dedicated equipment in isolation and quarantine rooms, handling and washing of laundry and eating utensils

#### 3. COVID-19 Control

- Testing protocol (for staff, consultants and visitors, and residents)
- Testing standing orders
- Review cohorting, quarantine, and isolation procedures

#### 4. Treatment for COVID-19 infections

- Medical directors should ensure that treatment of COVID is provided in accordance with evidence-based standards of care to mitigate risk of deterioration and death. This includes:
  - Creating a test to treat strategy in nursing home
  - Creating a program of clinical surveillance, early testing, and diagnosis (CDC guidance on diagnosis link)
  - Arranging for a supply for oral antivirals like Paxlovid and Molnupiravir within the nursing facility to ensure timely administration
  - Collaborating with and empowering consultant pharmacist to check positive residents for eligibility for the oral antivirals
  - Supporting coordination and consultation with patients' PCPs, nurse practitioners and physician assistants/associates regarding management of potential drug interactions
- Educate clinicians on standards of care in treatment of COVID in nursing home patients.
  - Discuss the creation of a goal concordant plan of care for COVID-19 infection
    - Discuss the options (mAbs, Paxlovid, Molnupiravir, Remdesivir)
    - Review a policy and procedure for IV treatments including mAbs and remdesivir, if IV treatments are an option in your facility
    - Discuss that mAbs may not be effective with new variant
    - Discuss specifics of each choice:
      - NIH Treatment Guidelines: <u>https://www.covidigtreatmentguidelines.nih.gov/management/clinical-management-of-adults/clinical-management-of-adults-</u> <u>summary/?utm\_source=site&utm\_medium=home&utm\_campaign=highlights</u>
    - Create a workflow in collaboration with nursing, pharmacy, and medical to evaluate, offer and initiate treatments for COVID-19. (Who reviews for interactions and renal dosing?)
    - ALL patients with a positive COVID test should be evaluated for treatment
      - Clinicians should consider treatment based on clinical conditions and not symptom severity. For older patients with frailty, waiting for symptoms to become severe may miss the window for treatment or miss the opportunity to prevent progression towards severe symptoms
      - Both vaccinated and unvaccinated patients will benefit from treatment
      - Rebound happens in both treated and untreated patients
      - Facility has access to these treatments in a timely manner; discuss how to order treatments and to contact the consultant pharmacist for further questions

- Educate staff, patients, and families:
  - WHAT: Discuss that there are options for treatment for a COVID-19 infection (may list the accessible options in your facility), and review risks versus benefits of all available treatments
  - WHY: Discuss why treatments are needed, even in mild cases, for high-risk patients (some cases start out mild but can progress to a severe illness needing hospitalization
  - WHO: Discuss who is high risk (immunocompromised, multiple comorbidities, lung/heart disease)
  - WHEN: Discuss the timing of the treatment (within 5 days for orals)
  - WHAT TO EXPECT: Discuss rebound and side effects (bad taste, upset stomach/nausea and decreased appetite)
  - WHERE we are now in the pandemic, how much transmission is happening in your area, and with winter and holidays coming, vaccination and treatment are the ways we save lives

#### 5. Collaboration opportunities

- Work with QIN-QIO team to survey educational needs of residents and staff and develop focused educational materials targeted to needs.
- Review the illness experiences and learn from the successes, near misses, and mistakes.
- Collaborate with health department as needed regarding access to PPE, tests, vaccines, and therapeutics and data sharing.