



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

November 14, 2022

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 bivalent booster 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 Assistants/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:**

- Frequently asked questions about the COVID-19 Bivalent Booster
- Bivalent Myths and Facts from Alliant Health Solutions (Link to Spanish version: https://quality.allianthealth.org/wp-content/uploads/2022/11/Bivalent-Myths-and-Facts-Spanish_508.pdf)
- 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
- Guidance on use of monoclonal antibodies to treat Omicron subvariants
- Role of the Medical Director in Effective Prevention & Treatment of COVID-19

2. **Additional Resources on Vaccinations:**

- Alliant Health Solutions: “Give the Boost a Shot” Campaign & Resources: <https://quality.allianthealth.org/topic/give-the-boost-a-shot/>
- FDA Fact Sheet on Emergency Use Authorization (EUA) of the Novavax COVID-19 Vaccine, adjuvanted to prevent COVID-19: <https://www.fda.gov/media/159898/download>
- Take 5 Video from Alliant Health Solutions on the Novavax Vaccine: <https://www.youtube.com/watch?v=gRDxEKnSZbA>
- Vaccine education materials from the Department of Health and Human Services as part of the “We Can Do This” initiative: <https://wecandothis.hhs.gov/>

3. **Additional Resources in Therapeutics:**

- Nebraska Antimicrobial Stewardship Assessment and Promotion Program: <https://asap.nebraskamed.com/covid-19-treatment/paxlovid/>
- ASPR: The Administration for Strategic Preparedness & Response: <https://aspr.hhs.gov/COVID-19/treatments>
- Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers: <https://www.fda.gov/media/158165/download>
- The COVID-19 Treatment Guidelines Panel’s Statement on Omicron Subvariants, Pre-Exposure Prophylaxis, and Therapeutic Management of Non-hospitalized Patients With COVID-19: <https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-omicron-subvariants/>

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:
<https://www.cdc.gov/flu/professionals/diagnosis/testing-management-considerations-nursinghomes.htm>

FAQs on the COVID-19 Omicron-Specific Bivalent Vaccine

1. What is it?
 - The new COVID-19 bivalent vaccine is a combination of ½ of the original vaccine and ½ of a new vaccine that is specific for the Omicron BA5/BA4 subvariants.
2. Why do we need it?
 - The COVID-19 virus continues to change and mutate.
 - The good news is we are learning more about the virus and developing better tools for both prevention and treatment.
 - Right now, the new COVID-19 bivalent vaccine is our **best protection** to prevent COVID-19 **reinfections, hospitalizations, and death** as well as **long COVID**.
 - It provides protection that appears to:
 - be better at protection against a different variant (broader protection),
 - last longer,
 - and provide improved protection by engaging more of our immune fighter cells.
3. Who should get it?
 - Anyone 5 years old and older who has received the initial COVID-19 vaccine series, either Pfizer, Moderna or Johnson & Johnson, **AND** is 2 months past their last vaccine shot. (Pfizer for 5 years old and older, Moderna for 6 years old and older)
 - Note: The previous booster shots are no longer available. The new COVID-19 bivalent vaccine is now the only booster shot that will be given.
4. What if you have recently had a COVID-19 infection?
 - You are eligible to get the new COVID-19 vaccine after you are feeling better and have completed your time in isolation. However, if you wait 3 months after your infection, you will get a better response from the new vaccine.
5. Can you mix and match vaccines?
 - Yes. It does not matter if you have had Moderna or Pfizer previously, you can get either the Moderna or Pfizer bivalent COVID-19 vaccine booster shot.
 - If you are a male under the age of 30, the Pfizer bivalent COVID-19 vaccine may have less risk of myocarditis (which is a rare occurrence).
6. Is it safe?
 - **Yes.** This new bivalent booster is similar to our new flu shot every year. It is the same type of vaccine, just an updated version.
7. What about side effects?
 - The information we have from the other COVID bivalent vaccine (½ the original and ½ BA1/BA2) shows **LESS** side effects than the original vaccination and monovalent booster shots.
 - The most common side effects are still headaches, fatigue, and muscle aches.
8. Will we continue to need booster shots?
 - It is likely that the COVID-19 vaccine will be an annual shot, just like the flu vaccine.

- It is important to understand that these new vaccine boosters are **what is now necessary to be protected from severe illness and death due to COVID.**
9. Does a patient need to have received a booster before receiving the bivalent booster?
No. Any patients who have completed their primary series at least two months ago can receive the bivalent vaccine.
10. Can patients who received multiple booster doses receive the bivalent booster?
Yes. A patient must wait two months after receiving any approved or authorized monovalent booster to receive the bivalent booster.
11. Can the monovalent boosters still be used?
No. The FDA has amended the EUAs and they no longer allow the use of monovalent boosters.
12. Can the bivalent booster be used as a primary immunization series?
No. The bivalent formula is only under EUA for use as a booster. The monovalent formula must be used for primary vaccination.
13. Are we in the “endemic” stage now, and if so, are vaccines really needed?
- We are trying to get to the “endemic” stage. Models now suggest that this winter could be better than previous COVID winters in terms of infection rates but a spike in infections is still anticipated.
 - BUT we are still seeing 100,000 people die each year from COVID infections, and that is still too many (compared to the flu, which causes about 30,000 deaths each year).
 - **We need to decrease transmission and the best and easiest way to do that is with vaccination.**
14. What should we expect for the future?
- Recommendations for better protection from COVID-19 infections will change, just as the virus continues to change and we get smarter about protection.
 - We should assume we are not done with adjusting our protection against COVID-19.
 - Doing our part and getting vaccinated as recommended allows us to reclaim our lives, our economy, and helps prevent stressing our healthcare system beyond its capacity.
 - When we increase our protection by getting the recommended booster shot, it not only protects us personally, but it helps restore the familiar way of life for our communities.
15. What about the flu this year? Is the flu shot still important?
- It is already a highly active flu season this year, as we are seeing a significant uptick in flu cases in the United States earlier this year than in the past.
 - It will be very important to get your flu shot.
 - If you are over 65, the CDC now recommends a **high dose** flu vaccine.
 - A Danish study has shown a 64% reduction in hospitalization in this age group for those who had a high dose flu shot compared to the regular dose flu shot
 - You can get the flu shot and the new bivalent COVID shot on the same day, just in different arms. This is safe and effective.
 - There is also data that shows that getting your flu shot each year can decrease your risk of dementia and other diseases.



Bivalent MYTHS AND FACTS



MYTH: The bivalent booster isn't necessary. I've already gotten two boosters, and I haven't gotten sick.

FACT: The effectiveness of monovalent booster decreases over time (approximately three months). Plus, the monovalent primarily provides immunity against the original COVID-19 virus. The bivalent (updated) booster offers immunity against the original COVID-19 virus AND the current omicron variant. Therefore, similar to new flu and pneumonia vaccines offering immunity against multiple variants, the updated COVID-19 booster is a more effective vaccine.

MYTH: Once I get the bivalent booster, I will have to get another one every two months.

FACT: You only need the bivalent (updated) booster once a year. The bivalent booster has broader immunity compared to the earlier monovalent boosters, which allows it to be a once-a-year booster.

MYTH: The bivalent booster isn't needed because the pandemic is over. The CDC says we don't have to wear masks anymore.

FACT: Masking remains an essential tool for preventing the spread of COVID-19 and other viruses, such as the flu. You may still be asked to wear a mask in a health care facility to protect vulnerable residents during periods of high transmission in the community. New strains of COVID-19 continue to emerge in the United States and worldwide. Many of them have the potential to cause significant outbreaks, as we have seen in the past. Getting vaccinated is the best way to stay safe from future outbreaks. Now that fewer people are wearing masks, it is even more critical to increase your immunity by being up-to-date with the latest booster.



MYTH: The bivalent booster increases cardiac-related death.

FACT: Becoming infected with COVID-19 increases the risk of myocarditis by 11 times. The COVID vaccine cuts this risk in half. Like the monovalent vaccine, the bivalent booster can cause a very rare chance of myocarditis, primarily for younger men. It is self-limiting, and there are no long-term effects.

MYTH: I hear that this flu season is supposed to be tough, and I want to get my flu shot. The bivalent booster will have to wait.

FACT: Since there has been a decline in flu rates due to people wearing masks, herd immunity may have been lowered. In addition, with fewer people wearing masks, the risk of flu and COVID-19 virus transmission has increased. It is advisable to get both the flu and the updated COVID-19 booster. You can safely receive both vaccines at the same time.

MYTH: COVID-19 no longer makes people very sick; it is like a cold, so I don't need the latest booster.

FACT: An increase in the number of people vaccinated against COVID-19 has significantly contributed to lowered hospitalization rates and deaths. The booster vaccine substantially reduces the risk of severe illness, hospitalization or death. However, unvaccinated people or people with certain medical conditions are still hospitalized and dying from COVID-19. In addition, many people are also developing Long COVID syndrome. The vaccine decreases all of these risks.

MYTH: I have already had COVID, so I have natural immunity. I don't need the booster.

FACT: With the new variants, the protection from natural immunity does not seem to hold up well. Further, the level and duration of natural immunity vary among people. Therefore, we cannot depend on natural immunity. The updated booster creates a predictable level of immunity against multiple strains of COVID-19, thus providing a better immunity level. As new variants develop, the updated booster offers more predictable coverage against COVID-19.



For more information on COVID-19 boosters, visit the CDC website: (insert QR code for link)https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html?s_cid=11747:bivalent%20vaccine;sem.ga;p:RG:GM:gen:PTN:FY22

Source: <https://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.122.059970>

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, treatment with Paxlovid reduced the risk of hospitalization or death by 88%. 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 patients²
- 75% reduction in death compared to non-users³

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.⁴

¹Ronza Najjar-Debbiny et al. *Clinical Infectious Diseases*, 2022;, ciac443, <https://doi.org/10.1093/cid/ciac443>

²Scott Dryden-Peterson et al. *medRxiv* 2022.06.14.22276393; doi: <https://doi.org/10.1101/2022.06.14.22276393>

³Carlos K.H. et al. *medRxiv* 2022.05.19.22275291; doi: <https://doi.org/10.1101/2022.05.19.22275291>

⁴Yan 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 but also occurs in patients receiving no treatment 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 [Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers](#) 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.

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

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: _____

Date of symptom onset:		Date of positive SARS-CoV-2 test:	
CHANGE IN BASELINE OXYGEN REQUIREMENTS? <input type="checkbox"/> No <input type="checkbox"/> 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)

<input type="checkbox"/> Older age (for example, age ≥50 years of age) <input type="checkbox"/> Obesity or being overweight (for example, BMI >25 kg/m ² , or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts) <input type="checkbox"/> Pregnancy <input type="checkbox"/> Chronic kidney disease <input type="checkbox"/> Diabetes <input type="checkbox"/> Immunosuppressive disease or immunosuppressive treatment <input type="checkbox"/> Cardiovascular disease (including congenital heart disease) or hypertension <input type="checkbox"/> Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension) <input type="checkbox"/> Sickle cell disease <input type="checkbox"/> Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies) <input type="checkbox"/> Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)) <input type="checkbox"/> 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 <input type="checkbox"/>	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 <input type="checkbox"/>	Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO ₂) ≥94% on room air at sea level.
Severe Illness	Individuals who have SpO ₂ <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO ₂ /FiO ₂) <300 mmHg, respiratory frequency >30 breaths per minute, or lung infiltrates >50%

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.
- 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:
 - 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.
 - The significant known and potential risks and benefits of Paxlovid, and the extent to which such risks and benefits are unknown.
 - Information on available alternative treatments and the risks and benefits of those alternatives including clinical trials.
 - 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 provider¹

¹The 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)
- 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) 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): _____

Paxlovid (nirmatrelvir; ritonavir) Treatment Order Form

PATIENT ID _____

Patient Name: _____ Date of Birth: _____

Facility: _____

Date of symptom onset:		Date of positive SARS-CoV-2 test:	
CHANGE IN BASELINE OXYGEN REQUIREMENTS? <input type="checkbox"/> No <input type="checkbox"/> 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)

<input type="checkbox"/> Older age (for example, age ≥ 50 years of age) <input type="checkbox"/> Obesity or being overweight (for example, BMI >25 kg/m ² , or if age 12-17, have BMI ≥ 85 th percentile for their age and gender based on CDC growth charts) <input type="checkbox"/> Pregnancy <input type="checkbox"/> Chronic kidney disease <input type="checkbox"/> Diabetes <input type="checkbox"/> Immunosuppressive disease or immunosuppressive treatment <input type="checkbox"/> Cardiovascular disease (including congenital heart disease) or hypertension <input type="checkbox"/> Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension) <input type="checkbox"/> Sickle cell disease <input type="checkbox"/> Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies) <input type="checkbox"/> Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)) <input type="checkbox"/> 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 <input type="checkbox"/>	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 <input type="checkbox"/>	Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO ₂) $\geq 94\%$ on room air at sea level.
Severe Illness	Individuals who have SpO ₂ $<94\%$ on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO ₂ /FiO ₂) <300 mmHg, respiratory frequency >30 breaths per minute, or lung infiltrates $>50\%$

Paxlovid (nirmatrelvir; ritonavir) Treatment Order Form

PATIENT ID _____

Patient Name: _____ Date of Birth: _____

Facility: _____

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 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:
 - 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.
 - The significant known and potential risks and benefits of Paxlovid, and the extent to which such risks and benefits are unknown.
 - Information on available alternative treatments and the risks and benefits of those alternatives including clinical trials.
 - 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 provider¹

¹The 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 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)
- 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) 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): _____

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

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

NO TO ANY

You may NOT order Paxlovid; refer the patient to a state-licensed physician, advanced practice registered nurse, or physician assistant

Transfer Consultant Pharmacist Note to prescribing provider along with recommendation for Paxlovid, if appropriate, and drug regimen changes, as necessary

YES TO ALL FOUR

You MAY order Paxlovid, in accordance with the EUA, Healthcare Provider Fact Sheet and PREP Act Declarations

Report order and use to primary care provider, if possible, and complete all necessary reporting to the U.S. Government

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 [here](#). (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
- Clopidogrel
- Disopyramide
- Dofetilide
- Dronedarone
- Eplerenone
- Flecainide
- Ivabradine
- Propafenone
- Quinidine
- Ranolazine
- Ticagrelor
- Vorapaxar

Neuropsychiatric

- Clozapine
- Lurasidone
- 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.

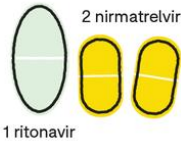
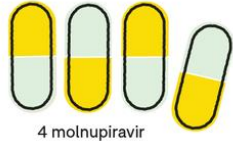











Additional Resources

[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	LAGEVRIO
1 What is it?	 <p>1 ritonavir 2 nirmatrelvir</p>	 <p>4 molnupiravir</p>
2 Who makes it?		
3 How does it work?	Blocks a protein the virus uses to multiply	Inserts itself into the virus's genetic material
4 Who can take it?	Adults & kids 12+ weighing 88+ lbs & at high risk 	Adults 18+ at high risk* 
5 How effective is it?	 <p>Lowers risk by almost 90%</p>	 <p>Lowers risk by about 30%</p>
6 Are there any drug interactions?	Many statins, blood thinners, hormonal birth controls, some seizure medications, St. John's wort**	Minimal
7 How much does it cost?	\$530	<p>Currently free to applicable patients during the COVID-19 public health emergency</p> \$700
8 How do you take it?	<p>AM </p> <p>PM </p>	<p>2x daily by mouth for 5 days</p> <p> AM</p> <p> PM</p>
9 What does it treat?	<p>MILD MODERATE SEVERE</p>	
10 How can you get it?	<p>Prescription only</p> 	

* Should only be used when no other treatment is available for mild to moderate COVID-19.
** Consult your doctor for other potential drug interactions.

Paxlovid Fact Sheet for Patients, Residents, and their Caregivers

Your healthcare provider believes you would benefit from taking Paxlovid for the treatment of mild-to-moderate 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 over-the-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.

Anti-SARS-CoV-2 Monoclonal Antibodies: Guidance regarding their use for treatment against Omicron subvariants (10/19/22)

On October 14, 2022, the Centers for Disease Control and Prevention (CDC) reported a rapid increase in certain SARS-CoV-2 Omicron subvariants circulating in the United States¹ that are likely to be resistant to some anti-SARS-CoV-2 monoclonal antibodies (mAbs):

- Subvariants BQ.1 and BQ.1.1 are likely to be resistant to bebtelovimab
- Subvariants BA.4.6, BA.2.75.2, BF.7, BQ.1, and BQ.1.1 are likely to be resistant to tixagevimab plus cilgavimab (Evusheld).

Although the proportions of these potentially resistant SARS-CoV-2 subvariants are increasing, their prevalence is currently low or moderate.

- The COVID-19 Treatment Guidelines Panel (the Panel) continues to recommend **bebtelovimab** for the treatment of COVID-19 **only when ritonavir-boosted nirmatrelvir (Paxlovid) or remdesivir cannot be used in non-hospitalized adults who are at high risk of progressing to severe COVID-19**. Paxlovid, remdesivir, and molnupiravir are expected to be active against these subvariants.

The Panel continues to recommend the anti-SARS-CoV-2 mAbs **tixagevimab plus cilgavimab as pre-exposure prophylaxis (PrEP)** for eligible individuals. Individuals who receive tixagevimab plus cilgavimab as PrEP should continue to take precautions to avoid infection. If they experience signs and symptoms consistent with COVID-19, they should be tested for SARS-CoV-2 and, if infected, promptly seek medical attention for consideration of antiviral treatment.

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
 - 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: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management-of-adults/clinical-management-of-adults-summary/?utm_source=site&utm_medium=home&utm_campaign=highlights
 - 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