December 2021

Oral Antiviral Treatments for COVID-19 – Emergency Use Authorization

Paxlovid (nirmatrelvir/ritonavir; Pfizer) and molnupiravir (Merck) are oral antiviral agents that have been granted emergency use authorization (EUA) by the FDA for the treatment of mild-to-moderate coronavirus disease (COVID-19). They are not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment of severe or critical COVID-19 requiring hospitalization.

Paxlovid is the preferred product, and molnupiravir can be considered for patients age 18 years and older for whom alternative FDA-authorized COVID-19 treatment options are not accessible or clinically appropriate. Paxlovid is associated with numerous significant drug-drug interactions (see Section 7 of fact sheet). Providers must be aware of these interactions and modify therapy as clinically appropriate.

<table>
<tr><th>Medication</th><th colspan="2">Paxlovid (nirmatrelvir/ritonavir)</th><th>Molnupiravir</th></tr>
<tr><td>EUA criteria</td><td colspan="2">Treatment of mild-to-moderate COVID-19 in adults and pediatric patients:
• Age ≥ 12 years weighing at least 40 kg / 88 lbs
• Positive results of direct SARS-CoV-2 testing, and high risk for progression to severe COVID-19, including hospitalization or death
• Should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset
• Patients must be provided with fact sheet</td><td>Treatment of mild-to-moderate COVID-19 in adult patients
• Age ≥ 18 years
• Positive results of direct SARS-CoV-2 testing, and high risk for progression to severe COVID-19, including hospitalization or death
• Should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset
• Patients must be provided with fact sheet</td></tr>
<tr><td rowspan="4">Dosing and Administration</td><td>eGFR (mL/min)</td><td>Dosing (with or without food)</td><td rowspan="4">800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food</td></tr>
<tr><td>≥60</td><td>300mg nirmatrevir/100mg ritonavir twice daily for 5 days</td></tr>
<tr><td>≥30 - <60</td><td>150mg nirmatrevir/100mg ritonavir twice daily for 5 days</td></tr>
<tr><td><30</td><td>Not recommended</td></tr>
<tr><td>Drug Interactions</td><td colspan="2">• Co-administration is contraindicated with drugs that are highly dependent on CYP3A for clearance (e.g certain anti-arrhythmics, statins) and for which elevated levels are associated with serious and/or life-threatening reactions
• Co-administration is contraindicated with drugs that are potent CYP3A inducers (e.g certain anticonvulsants, rifampin) and may be associated with the potential for loss of virologic response and possible resistance.
• Refer to Section 7 of the fact sheet for a complete list of drugs that should not be taken in combination.</td><td>No drug interactions have been identified based on limited available data. Drug-drug interaction studies have not been conducted.

In vitro study results indicate that molnupiravir is not a substrate of CYP enzymes or human P-gp and BCRP transporters.</td></tr>
<tr><td>Warnings/ Precautions</td><td colspan="2">Resistance to HIV protease inhibitors: Because nirmatrelvir is co-administered with ritonavir, there may be a risk of HIV-1 developing resistance to HIV protease inhibitors in</td><td>Embryo-Fetal Toxicity: may cause fetal harm when administered to pregnant individuals
• Advise individuals of childbearing potential of the potential risk to a fetus and to use</td></tr>
</table>

	individuals with uncontrolled or undiagnosed HIV-1 infection. Liver disease: Paxlovid is not recommended in patients with severe liver impairment (Child-Pugh Class C). Ritonavir may cause liver damage, so caution should be exercised when giving Paxlovid to patients with preexisting liver diseases, liver enzyme abnormalities or liver inflammation	contraception during treatment and for 4 days after the final dose. Bone and Cartilage Toxicity: not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth
Side Effects	Possible side effects include impaired sense of taste, diarrhea, high blood pressure and muscle aches	Diarrhea, nausea and dizziness
Please refer to the FDA Fact Sheets for Healthcare Providers: Emergency Use Authorization for more information: • Paxlovid: https://www.fda.gov/media/155050/download • Molnupiravir: https://www.fda.gov/media/155054/download		

Eligible patients should test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate.

After confirming a positive test for SARS-CoV-2 and patient eligibility, complete the following steps to prescribe an oral antiviral medication for a patient:

1. Locate and add **Alto Pharmacy** to your prescribing platform:
- Address:100 Park Avenue, Front E, NY, NY 10017
- Phone: 800-874-5881
- Fax: 415-484-7058
- NPI: 1417578899
- NCPDP: 5831866

2. Verify patient's phone number and address for delivery.

3. In the note for pharmacist section, indicate the patient's:
- Race/ethnicity from the following options: Asian/Native Hawaiian or other Pacific Islander; Black; Hispanic/Latino; Native American/Alaska Native; and White
- Date of symptom onset

4. Choose the oral antiviral. Providers who would like to automatically have molnupiravir substituted when Paxlovid is unavailable must submit two prescriptions, one for each medication, and state in the notes section of the molnupiravir prescription, ***"to be used in case Paxlovid prescription cannot be filled because of supply limitation."*** Substituting with molnupiravir can only be done for patients meeting eligibility criteria and with no contraindications for either product.

5. Submit prescription to Alto Pharmacy.

6. Advise patient that they will receive a call or text message from the pharmacy (800-874-5881) and they must respond to schedule the delivery. More information is available at the Alto Pharmacy website.

7. Contact Alto Pharmacy at 800-874-5881 for questions or concerns.

The U.S. Department of Health and Human Services (HHS) provides oral antivirals at no cost to patients. Prescriptions in New York City (NYC) will be filled by **Alto Pharmacy** to provide free, same day home delivery.