



January 20, 2022

To: San Joaquin County Health Care Providers
From: Maggie Park, M.D., Health Officer 
Subject: COVID-19 Oral Antiviral Medications

Dear Colleagues:

Two recently FDA authorized oral medications for the treatment of outpatients with mild-to-moderate COVID-19 at risk for progression to severe disease are available in San Joaquin County. These medications are Paxlovid and Molnupiravir.

- **Paxlovid** (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) is an oral protease inhibitor. Pfizer announced the results from a trial of 2,246 adults who received either Paxlovid or placebo. All patients had not received a COVID-19 vaccine and had not been previously infected with COVID-19. In the study, Paxlovid significantly reduced the proportion of people with COVID-19 related hospitalization or death from any cause by 88% compared to placebo among patients treated within five days of symptom onset.

Paxlovid has received an EUA authorizing use for the treatment of mild-to-moderate COVID-19 in patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing and at high risk for progression to severe COVID-19, including hospitalization or death.

- **Molnupiravir** is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis. Merck announced results from a trial of 1,433 patients. Enrolled participants had not received a COVID-19 vaccination and had at least one risk factor associated with poor disease outcomes and symptom onset within five days prior to study enrollment. The risk of hospitalization for any cause or death through day 29 was lower with molnupiravir (6.8%) than with placebo (9.7%), for a relative risk reduction of 30%.

Molnupiravir is authorized for treatment of mild-to-moderate COVID-19 in adults (patients 18 years of age and older) with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.



Instructions to Providers

Both oral antivirals may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Paxlovid and molnupiravir belong (i.e., anti-infectives).

Providers should carefully review the fact sheet for healthcare providers (available both for Paxlovid and molnupiravir) before prescribing either medication to ensure that the patient's condition warrants treatment, that there are no drug interactions, and that there are no contraindications to therapy.

The use of molnupiravir is not recommended during pregnancy. Advise individuals of childbearing potential to use effective contraception correctly and consistently, as applicable, for the duration of treatment as described in the FDA fact sheets. Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

Patients meeting these criteria may be eligible for treatment with Paxlovid or Molnupiravir:

- Symptomatic with mild to moderate COVID-19 AND
- Positive results of direct SARS-CoV-2 viral testing AND
- At high risk for progressing to severe COVID-19 and/or hospitalization

The definition of mild and moderate disease, defined by National Institutes of Health as:

- 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 an oxygen saturation (SpO₂) ≥94% on room air at sea level.

The FDA has not authorized Paxlovid or Molnupiravir for treatment in patients requiring hospitalization due to severe or critical COVID-19.

For a complete list of risk factors for disease progression, including information on the relative risk of severe disease, see the CDC webpage for "Underlying Medical Conditions Associated with High Risk for Severe COVID-19" located at: emergency.cdc.gov/coca/calls/2021/callinfo_052721.asp.

Molnupiravir is only authorized for use if alternative COVID-19 treatment options authorized by FDA are not accessible or are not clinically appropriate.



Supply and Availability

Supply of these products is extremely limited. The following pharmacies in San Joaquin County are currently receiving allocations of Paxlovid and Molnupiravir:

- CVS 9256 100 W Lodi Ave, Lodi
- CVS 1175 W Lathrop Rd, Manteca
- CVS 1190 N Main St, Manteca
- CVS 2605 West March Lane, Stockton
- CVS 3320 N Tracy Blvd, Tracy
- CVS 6632 Pacific Ave, Stockton
- Rite Aid 6455 Pacific Avenue, Stockton
- Kaiser Hospital Manteca 1777 West Yosemite Ave, Manteca
- KPNC Tracy Medical Offices 2185 W Grant Line Rd, Tracy
- Kaiser Permanente – Stockton 7373 West Ln, Stockton

Paxlovid, which is the preferred oral antiviral for treatment of the Omicron variant is in extremely short supply. Providers prescribing Paxlovid should consider authorizing Molnupiravir as an alternate substitution to maximize the opportunity for patients to receive therapy during their treatment window.

FDA Fact Sheets

Paxlovid: www.fda.gov/media/155050/download

Molnupiravir: www.fda.gov/media/155054/download

NIH COVID-19 Treatment Guidelines

www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/