COUNTY OF YOLO

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Health Advisory

Date: December 28, 2021
To: Yolo County Healthcare Providers
From: Dr. Aimee Sisson, Health Officer
Subject: Oral Antivirals for Treatment of COVID-19

SUMMARY: The FDA recently granted Emergency Use Authorization for 2 oral antivirals for the treatment of mild to moderate COVID-19. Initial quantities of antivirals will be extremely limited.

BACKGROUND: On December 22, the U.S. Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for Paxlovid (nirmatrelvir tablets and ritonavir tablets co-packaged for oral use) from Pfizer. On December 23, the FDA issued an EUA for molnupiravir from Merck. Both Paxlovid and molnupiravir are authorized for the treatment of mild-to-moderate COVID-19 in those who are at high risk of progressing to severe COVID-19, including hospitalization or death. Neither medication is authorized for treatment of patients hospitalized due to COVID-19.

Both Paxlovid and molnupiravir will soon be available by prescription in Yolo County. However, initial quantities will be extremely limited. Yolo County's first allocation of Paxlovid will consist of 20 courses, and will be available only at Rite Aid at 295 West Main Street in Woodland. Yolo County's first allocation of molnupiravir will consist of 140 courses, and will be available at Rite Aid at 295 West Main Street in Woodland and at Winters Healthcare. The California Department of Public Health (CDPH) has communicated to local health jurisdictions that future allocations will be larger and will be distributed to additional pharmacies, but no additional details are available.

While quantities of Paxlovid and molnupiravir remain extremely limited, healthcare providers should prioritize the limited supply for high-risk patients with moderate illness (as defined below) in the following order:

1. Immunocompromised or on immunosuppressive medications
2. Incompletely vaccinated AND > 65 years of age with risk factors for severe disease
3. > 65 years of age with risk factors for severe disease

Moderate illness is defined as 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 CDC considers the following to be among the risk factors for severe COVID-19, and notes that the likelihood of developing severe COVID-19 increases when a person has multiple comorbidities:

- age (risk increases with each decade after age 50)
- cancer
- cardiovascular disease
- chronic kidney disease
- chronic lung disease
- diabetes
- immunocompromising conditions or receipt of immunosuppressive medications
- obesity (body mass index ≥30)
- pregnancy
- sickle cell disease

Providers should review the complete EUA and Fact Sheet before prescribing either antiviral medication. Providers should also confirm the diagnosis of COVID-19 with a positive result on direct SARS-CoV-2 viral testing before prescribing Paxlovid or molnupiravir.

Paxlovid is comprised of nirmatrelvir, a SARS-CoV-2 main protease inhibitor, co-packaged with ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. Paxlovid is authorized for use in adults and children 12 and older weighing at least 40 kg. Paxlovid is administered as a 5-day treatment course of 3 tablets twice daily. Treatment must begin within 5 days of symptom onset. In a clinical trial, Paxlovid reduced the proportion of people with COVID-19 hospitalization or death by 88% compared to placebo among patients treated within 5 days of symptom onset. Paxlovid inhibits CYP3A and is contraindicated with drugs that induce CYP3A or depend on CYP3A for clearance. The dosage of Paxlovid should be adjusted in patients with moderate renal impairment.

Molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis. Molnupiravir is authorized for use in adults 18 and older. Molnupiravir is administered as a 5-day treatment course of 4 capsules twice daily. Treatment must begin within 5 days of symptom onset. Molnupiravir may cause fetal harm when administered to pregnant individuals and is not recommended during pregnancy. In a clinical trial, molnupiravir reduced the risk of hospitalization or death by 30% compared to placebo.

RESOURCES:
Paxlovid EUA
Paxlovid Prescribing Information
Paxlovid Dear Healthcare Provider Letter
Paxlovid Fact Sheet for Patients
Molnupiravir EUA
Molnupiravir Prescribing Information
Molnupiravir Dear Healthcare Provider Letter
Molnupiravir Fact Sheet for Patients