PAXLOVID FAQs

What is PAXLOVID?

PAXLOVID is a combination of two oral antivirals (nirmatrelvir and ritonavir) for the treatment of non-hospitalized patients with mild to moderate COVID-19. The FDA recently authorized an emergency use authorization (EUA) for use in adults and pediatric patients (12 years of age and older weighing at least 40kg) with confirmed COVID-19 infection and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Who is eligible for PAXLOVID?

Eligibility for PAXLOVID will be determined based on our supply and guidance from our state or county public health departments. Given limited supply, it will be prioritized for patients who are at high risk for progression to severe COVID-19.

Eligible patients:

- Must be 12 years or older (or at least 40kg)
- Have a positive COVID-19 test,
- Are at high risk for severe COVID-19 (NIH Tiers 1-4)
- Have symptoms of mild/moderate COVID-19
- Are within 5 days of symptom onset

Paxlovid is not authorized:

- For initiation of treatment in patients hospitalized due to COVID-19
- For initiation of treatment in patients with a positive COVID-19 test but no symptoms of COVID-19
- For use for longer than 5 consecutive days
- For pre-exposure or post-exposure prophylaxis for prevention of COVID-19
- Avoid in patients with severe renal impairment (GFR<30mL/min)
- Avoid in patients with severe hepatic impairment (e.g. Child-Pugh Class C)

Can paxlovid be prescribed pre-emptively for patients without a positive COVID-19 test in case of future COVID-19?

No. Paxlovid is not authorized for use in patients without a diagnosis of COVID-19 and should not be prescribed in the absence of a positive test. Patients at risk for acquiring COVID-19 should be counseled to monitor for COVID-19 symptoms and get tested as soon as possible after symptom onset. Patients should notify their provider immediately of a positive result so that paxlovid can be prescribed to eligible patients within 5 days of symptom onset.

Is Paxlovid FDA approved?

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FDA has issued an EUA for the emergency use of the unapproved product paxlovid. Emergency use authorization is NOT the same as FDA approval or licensure. Since the drug is not FDA approved, there are specific requirements for documentation.

Providers prescribing paxlovid must review the patient fact sheet found at https://www.fda.gov/media/155050/download, discuss the medication is authorized under Emergency use authorization, and there are alternatives to paxlovid.

Providers should use the smartphrase called .COVID19ORALTHERAPYASSESSMENT to document the patient conversation.

A copy of the FDA Fact Sheets for Patients, Parents and Caregivers will be provided at pharmacy pickup and is available online at:

- https://www.fda.gov/media/155051/download (English)
- https://www.fda.gov/media/155075/download (Spanish)

What are the data supporting the use of PAXLOVID?

The EPIC-HR trial, a Phase 2/3 study compared paxlovid(n=1,109) in a 1:1 fashion to placebo(n=1,115), in unvaccinated adults with mild/moderate COVID-19 infection who had at least one-risk factor for progression COVID-19 severe illness. Patients had to be treated within 5 days of symptom onset. The primary outcome analysis indicated that PAXLOVID significantly reduced the risk of COVID-19 related hospitalization or death by 88% when compared to placebo; 8(0.8%) in the paxlovid group vs. 66 (6.3%) in the placebo arm. All-cause mortality occurred in 0(0%) in the paxlovid group vs. 12(1.1%) in the placebo arm. Paxlovid was well tolerated with no appreciable difference in discontinuation between adverse between paxlovid and placebo (2% vs 4%).This study was conducted prior to the emergence of the Omicron variant.

What are side effects of PAXLOVID?

PAXLOVID was well tolerated in the clinical trial. The most common adverse effects were dysgeusia, diarrhea, hypertension and myalgia. However, there are limited clinical data available for paxlovid so serious and unexpected adverse events may occur that have not been previously reported. If a patient experiences a serious side effect, the FDA must be notified by filling out an online form.

Are there drug-drug interactions with PAXLOVID?

There are many clinically significant drug-drug interactions with PAXLOVID. It is very important to review the complete list of the patient's medications to determine if PAXLOVID is contraindicated or if dose adjustment is needed for other medications while taking PAXLOVID.

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Ritonavir may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception.

Patients should be advised to not start new medications while on Paxlovid without review by their provider.

What is the dose and duration of PAXLOVID?

The dosage is 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together, orally twice daily for 5 days (with or without food). Dose adjustment is needed for CrCl of 30-60mL/min: Nirmatrelvir 300 mg BID should be dose reduced to 150 mg BID; ritonavir dosing remains unchanged. PAXLOVID should not be used in those with a CrCl is < 30 mL/min.

Treatment course should be initiated as soon as possible after a diagnosis of COVID-19 and within 5 days of symptom onset.

If PAXLOVID is ordered through SCCA pharmacy will PAXLOVID be picked up or delivered?

Both delivery service and curbside pickup is available at SCCA outpatient pharmacy. Last updated 3.6.2022

Additional information:
Healthcare fact sheet: https://www.fda.gov/media/155050/download

Patient fact sheet:

https://www.fda.gov/media/155051/download

https://www.fda.gov/media/155075/download

NIH guidelines for treatment:

https://www.covid19treatmentguidelines.nih.gov/

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