Paxlovid Quick Point-of-Care Reference

Last reviewed: 03/26/2024

Nirmatrelvir/ritonavir (brand name Paxlovid™) is FDA approved to treat mild-to-moderate COVID-19.

CLINICAL INFORMATION

Eligibility: Adults and pediatric patients 12 years and older weighing at least 40 kg (88 lb) who have a clinical diagnosis of COVID-19 and are at high risk for progression to severe COVID-19.

Note: A positive test is not required for use.

Nirmatrelvir/ritonavir is not recommended for patients with severe renal impairment or Child-Pugh Class C liver impairment due to lack of data.

Dosing: As below, the nirmatrelvir component of Paxlovid should be reduced to 150 mg twice daily in setting of renal impairment:



EGFR (CKD-EPI formula)	Dose of nirmatrelvir/ritonavir		
>60 mL/min	300 mg nirmatrelvir + 100 mg ritonavir, twice daily for 5 days*		
30≤60 mL/min	nin 150 mg nirmatrelvir + 100 mg ritonavir, twice daily for 5 days*		
<30 mL/min Not recommended: Appropriate dosing has not been determined.			

^{*} Courses of nirmatrelvir/ritonavir longer than 5 consecutive days are not FDA-authorized or approved.

Clinical Decision-Making: In ambulatory patients with mild-to-moderate COVID-19 at high risk for progression to severe disease, both FDA approval and <u>clinical guidelines</u> indicate Paxlovid should be given as soon as possible after diagnosis and within 5 days of symptom onset. Nirmatrelvir/ritonavir is recommended regardless of vaccination status.¹

The Real-Time Learning Network's <u>COVID-19 Outpatient Treatment Guidelines Roadmap</u> and HHS's <u>COVID-19 Therapeutics</u> <u>Clinical Decision Aid</u> offer paths to evaluate current U.S. treatment options.

DRUG-DRUG INTERACTION

Safe use of Paxlovid in eligible populations requires evaluation of drug-drug interactions. Many interactions can be managed, though some are true contraindications including certain antiseizure drugs, blood thinners, antipsychotics, and cardiovascular drugs. If a patient's medications require dose changes for safe coadministration with nirmatrelvir/ritonavir, then a pharmacist may not prescribe it.

Drug-Drug Interaction Resources



FDA Patient Eligibility Screening Checklist Tool for Prescribers [PDF]

This printable checklist includes a patient screening guide and lists drugs with significant interactions. Drugs are listed as either contraindicated or as requiring additional management (i.e., avoiding or holding of the drug, dose adjustment or special monitoring).



IDSA Clinical Guide to Management of Nirmatrelvir/Ritonavir Drug Interactions

This clinical reference lists steps to minimize interaction risks and provides information on the management of commonly prescribed medications known to interact with nirmatrelvir/ritonavir.



HIVMA Treatment Considerations for People With HIV & Hepatitis C

This resource outlines considerations for treating COVID-19 in people with HCV or HIV and how to handle their ART and HCV medications.



SIDE EFFECTS

Commonly reported side effects of Paxlovid include dysgeusia (changes in taste) and gastrointestinal symptoms such as diarrhea. In clinical trials, overall adverse events were not more common with use of Paxlovid (2%, versus 4% with placebo).

SAFETY

"Rebound" Syndromes Following Paxlovid Use²

Some patients with COVID-19 who receive antiviral therapies, such as Paxlovid, can develop recurrent symptoms or newly positive testing in the days following therapy completion. The precise frequency of this "rebound" is not clear; this syndrome can also occur in patients not treated with antivirals.

Given rebound is occasionally associated with high viral loads, it is recommended that patients who develop a newly positive test or symptoms post Paxlovid therapy observe isolation policies similar to that surrounding their initial infection.

Regardless, it appears that rebound syndromes are neither associated with severe disease nor driven by resistant virus. Therefore concerns about rebound are not recommend grounds to avoid taking Paxlovid if eligible.

SUPPLY & ACCESS

Distribution: Paxlovid is currently widely available in the U.S. For current supply information intended for health providers, see HHS's COVID-19 Therapeutics Locator; the general public may use HHS's <u>Test-to-Treat locator</u> or view <u>HHS's COVID-19 Public Therapeutics Locator</u>.

Effective March 8th, 2024, the Paxlovid EUA will be rescinded, after which all EUA-labeled drug will need to be returned or disposed. Only "NDA" labeled drug can be given; this remains the same drug and formulation as the EUA drug.

Through December 31st, 2024, the PAXCESS free Paxlovid program will continue to provide free drug to eligible persons.

CODING & BILLING

Coding:

Drug Name	Dosage	Package Size	NDC
Paxlovid EUA	300-100 mg	6 tablets	00069-1085-06
Paxlovid EUA	300-100 mg	30 tablets	00069-1085-30

Billing: Paxlovid has been added by the Health and Human Services Commission to the Medicaid and Children's Health Insurance Program formularies as a payable pharmacy benefit.

FURTHER INFORMATION

Real-Time Learning Network Paxlovid Literature Reviews

CDC Webpage: Covid-19 Treatments and Medications

FDA Fact Sheet for Patients, Parents, and Caregivers [PDF]

HHS Fact Sheet on Paxlovid Eligibility and Effectiveness [PDF]

² Harrington PR, Cong J, Troy SB, et al. Evaluation of SARS-CoV-2 RNA Rebound After Nirmatrelvir/Ritonavir Treatment in Randomized, Double-Blind, Placebo-Controlled Trials — United States and International Sites, 2021–2022. MMWR Morb Mortal Wkly Rep 2023;72:1365–1370. DOI: https://dx.doi.org/10.15585/mmwr.mm7251a2



¹ Ganatra, August 2022