PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS CoV-2 viral testing, and who are at high-risk for progression to severe COVID-19, including hospitalization or death.

The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

Legend:

- **Meets criteria**
- **Does not meet criteria**

### How severe is the patient’s illness?

- **Asymptomatic/Presymptomatic**
- **Mild**
- **Moderate**
- **Severe**
- **Critical**

For more information on the Clinical Spectrum of SARS-CoV-2 Infection, see NIH resource [here](https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/).

NIH Guidelines do not necessarily reflect the PAXLOVID FDA Authorized Fact Sheet. Guidelines may be subject to change.

### What is the patient’s age?

- **Adult**
- **Pediatric ≥12 years & ≥40 kg (88 lb)**
- **Pediatric <12 years & <40 kg (88 lb)**

### What was the result of the patient’s COVID-19 viral testing?

- **Positive**
- **Negative**

### What is the patient’s risk for progression to severe COVID-19?

- **High risk**
- **Standard risk**

For more information on potential risk factors for severe illness or complications, see CDC guidance [here](https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/assessing-risk-factors.html).

NIH Guidelines do not necessarily reflect the PAXLOVID FDA Authorized Fact Sheet. Guidelines may be subject to change.

### When did symptoms begin?

- **Within the last 5 days**
- **Prior to the last 5 days**

The 5-day treatment course of PAXLOVID should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset.

### Does the patient have any contraindications?

- **No**
- **Yes**

Consult the Fact Sheet for Healthcare Providers for comprehensive information.

### Important Dosing Information in Patients with Renal Impairment

No dosage adjustment is needed in patients with **mild** renal impairment (eGFR ≥60 to <90 mL/min). In patients with **moderate** renal impairment (eGFR ≥30 to <60 mL/min), the dosage of PAXLOVID is 150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days. Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID. Providers should counsel patients about renal dosing instructions.

PAXLOVID is not recommended in patients with **severe** renal impairment (eGFR <30 mL/min) until more data are available; the appropriate dosage for patients with severe renal impairment has not been determined.

### Important Information Related to Drug Interactions

In the EUA Fact Sheet for Healthcare Providers, you’ll find a table for clinically significant drug interactions, including contraindicated drugs. This table contains drug classes in alphabetical order, drugs within each class, their effect on concentration of concomitant medications or PAXLOVID, and clinical comments. The clinical comments provide potential adverse events that may result for an interaction and provide recommendations, where applicable, to manage these drug interactions. Drugs listed in the table are a guide and not considered a comprehensive list of all possible drugs that may interact with PAXLOVID. The healthcare provider should consult appropriate references for comprehensive information.

Fact Sheet for Healthcare Providers
Fact Sheet for Patients, Parents, and Caregivers
FDA Emergency Use Authorization Letter

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