

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

This checklist is intended as an aid to support clinical decision making for prescribers. However, use of this checklist is not required to prescribe PAXLOVID under the EUA.

Medical History

- Positive SARS-CoV-2 test (Confirmation of a positive home rapid SARS-CoV-2 test result with additional direct SARS-CoV-2 viral testing is not required.)
- Age \geq 18 years OR \geq 12 years of age and weighing at least 40 kg
- Has one or more risk factors for progression to severe COVID-19¹ (Healthcare providers should consider the benefit-risk for an individual patient.)
- Symptoms consistent with mild to moderate COVID-19²
- Symptom onset within 5 days (Prescriber is encouraged to include a note to the pharmacist in the prescription stating: Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.)
- Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- No known or suspected severe renal impairment (eGFR \leq 30 mL/min)
 - Note that a dose reduction is required for patients with moderate renal impairment (eGFR \geq 30- $<$ 60 mL/min); see the Fact Sheet for Healthcare Providers.
 - To assess renal function:
 - Physicians, advanced practice registered nurses, and physician assistants who are licensed or authorized under state law to prescribe drugs may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of renal impairment. Providers may consider ordering a serum creatinine or calculating the estimated glomerular filtration rate (eGFR) for certain patients after assessment on a case-by-case basis based on history or exam.
 - State-licensed pharmacists must have sufficient information available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient; see the Fact Sheet for Healthcare Providers.
- No known or suspected severe hepatic impairment (Child-Pugh Class C)
 - To assess hepatic impairment:
 - Physicians, advanced practice registered nurses, and physician assistants who are licensed or authorized under state law to prescribe drugs may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of hepatic impairment.
 - State-licensed pharmacists must have sufficient information available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient; see the Fact Sheet for Healthcare Providers.
- No history of clinically significant hypersensitivity reactions [e.g., toxic epidermal

¹ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>

² <https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/#:~:text=Patients%20with%20mild%20illness%20may,on%20exertion%2C%20or%20abnormal%20imaging>

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necrolysis (TEN) or Stevens-Johnson syndrome] to the active ingredients (nirmatrelvir or ritonavir) or other components of the product

NOTES: _____

Concomitant Medications

NOTE: The state-licensed pharmacist should refer an individual patient for clinical evaluation (e.g., telehealth, in-person visit) with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if:

- Sufficient information is not available to assess for a potential drug interaction
- Modification of other medications is needed due to a potential drug interaction.
- PAXLOVID is not an appropriate therapeutic option based on the authorized Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

See the Fact Sheet for Healthcare Providers for the full Limitations of Authorized Use.

HMG-CoA reductase inhibitors (statins)

- *If the patient is taking lovastatin or simvastatin*, which are contraindicated with PAXLOVID coadministration, PAXLOVID can be given if the statin can be held 12 hours prior to the first dose of PAXLOVID treatment, held during the 5 days of treatment, and restarted 5 days after completing PAXLOVID.
- *If the patient is taking atorvastatin or rosuvastatin*, consider temporary discontinuation of atorvastatin and rosuvastatin during treatment with PAXLOVID. Atorvastatin and rosuvastatin do not need to be held prior to or after completing PAXLOVID.

Hormonal contraceptives containing ethinyl estradiol: *If the patient is taking a hormonal contraceptive containing ethinyl estradiol*, consider an additional non-hormonal method of contraception during the 5 days of PAXLOVID treatment and until one menstrual cycle after stopping PAXLOVID.

Medications for HIV-1 Treatment: *If the patient is taking medications for the treatment of HIV-1 infection*, with the exception of maraviroc³, HIV antiretroviral medications can be co-administered with PAXLOVID without dose adjustment, but arranging follow-up by the HIV care provider to monitor for side effects is recommended.^{4,5,6}

³ Please see the maraviroc prescribing information here:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022128Orig1s019,208984Orig1s002lbl.pdf

⁴ Exposure of certain HIV medications may be altered with PAXLOVID co-administration.

⁵ Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

⁶ PAXLOVID use may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

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Drug	Drug Class	Interaction Code
lidocaine (systemic)	Antiarrhythmic	***
lomitapide	Microsomal triglyceride transfer protein (MTTP) inhibitor	XXX
lumacaftor/ivacaftor	Cystic fibrosis transmembrane conductance regulator potentiator	XXX
lurasidone	Antipsychotic	XXX
methadone	Narcotic analgesic	***
methylergonovine	Ergot derivative	XXX
methylprednisolone	Systemic corticosteroid	***
midazolam (administered parentally)	Sedative/hypnotic	***
midazolam (oral)	Sedative/hypnotic	XXX
mometasone	Systemic corticosteroid	***
naloxegol	Opioid antagonist	XXX
neratinib	Anticancer drug	***
nicardipine	Calcium channel blocker	***
nifedipine	Calcium channel blocker	***
nilotinib	Anticancer drug	***
ombitasvir/paritaprevir /ritonavir	Hepatitis C direct acting antiviral	***
oxycodone	Narcotic analgesic	***
pethidine	Analgesic	XXX
phenobarbital	Anticonvulsant	XXX
phenytoin	Anticonvulsant	XXX
pimozide	Antipsychotic	XXX
primidone	Anticonvulsant	XXX
propafenone	Antiarrhythmic	XXX
quetiapine	Antipsychotic	***
quinidine	Antiarrhythmic	XXX
ranolazine	Antianginal	XXX
rifabutin	Antimycobacterial	***
rifampin	Antimycobacterial	XXX
rifapentine	Antimycobacterial	***
rimegepant	Migraine medication	***
rivaroxaban	Anticoagulant	***
salmeterol	Long-acting beta-adrenoceptor agonist	***
Sildenafil (when used for erectile dysfunction)	PDE5 inhibitor	***
sildenafil (Revatio®) when used for pulmonary arterial hypertension	PDE5 inhibitor	XXX
silodosin	Benign prostatic hyperplasia agent	XXX
sirolimus	Immunosuppressant	***

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Drug	Drug Class	Interaction Code
sofosbuvir/velpatasvir/ voxilaprevir	Hepatitis C direct acting antiviral	***
St. John's Wort (hypericum perforatum)	Herbal product	XXX
suvorexant	Neuropsychiatric agent	***
tacrolimus	Immunosuppressant	***
tadalafil	PDE5 inhibitor	***
tamsulosin	Alpha 1-adrenoreceptor antagonist	***
tezacaftor/ivacaftor	Cystic fibrosis transmembrane conductance regulator potentiator	***
ticagrelor	Cardiovascular agent	***
tolvaptan	Vasopressin receptor antagonist	XXX
trazodone	Antidepressant	***
triamcinolone	Systemic corticosteroid	***
triazolam	Sedative/hypnotic	XXX
ubrogepant	Migraine medication	XXX
vardenafil	PDE5 inhibitor	***
venetoclax	Anticancer drug	***
vinblastine	Anticancer drug	***
vincristine	Anticancer drug	***
voclosporin	Immunosuppressant	XXX
vorapaxar	Cardiovascular agent	***
voriconazole	Antifungal	***
warfarin	Anticoagulant	***

ADDITIONAL RESOURCES:

PAXLOVID - Fact Sheet for Healthcare Providers: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>

Prescribing Information (Label/Package Insert) for Individual Drugs (Drugs@FDA): <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>

University of Liverpool COVID-19 Drug Interactions: <https://www.covid19-druginteractions.org/checker>

NIH COVID-19 Treatment Guidelines: <https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid/>