

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.

Medical History

- Has mild to moderate COVID-19 (symptomatic SARS-CoV-2 infection not requiring hospitalization).
- 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
- 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 necrolysis (TEN) or Stevens-Johnson syndrome] to the active ingredients (nirmatrelvir or ritonavir) or other components of the product

NOTES:

Concomitant Medications

¹ Determining whether a patient is at high risk for progression to severe COVID-19, including hospitalization or death, is based on the provider's assessment of the individual patient being considered for treatment of COVID-19 and that patient's medical history. For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

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 and USPI 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*, consider temporary discontinuation of atorvastatin during treatment with PAXLOVID. Atorvastatin 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 maraviroc², 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.^{3,4,5}

² Please see the maraviroc prescribing information here:

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

³ Exposure of certain HIV medications may be altered with PAXLOVID co-administration.

⁴ Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

⁵ 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.

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

- Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID
 - Patient is not taking any other medications
 - Patient is not taking any of the medications listed below.
 - In addition, the patient's other medications have been checked for contraindications, the need for dose adjustment, or increased monitoring due to drug interactions with a strong CYP3A inhibitor such as ritonavir based on appropriate resources such as the prescribing information of these medications.
 - Patient is NOT taking any of the medications listed in RED but is taking one or more of the medications listed below in YELLOW, and dose adjustment, holding of medication, or increased monitoring is planned (additional resources which include instructions for managing specific drug interactions are included at the end of this document).
 - In addition, the patient's other medications not listed below have been checked for contraindications, the need for dose adjustment, or increased monitoring due to drug interactions with a strong CYP3A inhibitor such as ritonavir based on appropriate resources such as the prescribing information of these medications.

NOTES:

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID (listed alphabetically by generic name)

Interaction Codes:



Coadministration of this drug with PAXLOVID is CONTRAINDICATED. For further information, refer to the Fact Sheet for Healthcare Providers and the individual Prescribing Information for the drug.



Coadministration of this drug with PAXLOVID should be avoided and/or holding of this drug, dose adjustment of this drug, or special monitoring is necessary. Consultation with the prescriber of the potentially interacting drug is recommended. For further information, refer to the Health Care Provider Fact Sheet, the USPI, and the individual Prescribing Information for the drug.

*The table below provides a listing of clinically significant drug interactions, including contraindicated drugs, in addition to those listed under Concomitant Medications above (HMG-CoA reductase inhibitors [statins], hormonal contraceptives containing ethinyl estradiol, and medications for HIV-1 treatment). **Drugs listed in this table are a guide and are not considered a comprehensive list of all possible drugs that may interact with PAXLOVID. The healthcare provider should consult other appropriate resources such as the prescribing information for the interacting drug for comprehensive information on dosing or monitoring with concomitant use of a strong CYP3A inhibitor such as ritonavir.***

Drug	Drug Class	Interaction Code
abemaciclib	Anticancer drug	***
alfuzosin	Alpha 1-adrenoreceptor antagonist	XXX
aliskiren	Cardiovascular agent	***
amiodarone	Antiarrhythmic	XXX
amlodipine	Calcium channel blocker	***
apalutamide	Anticancer drug	XXX
apixaban	Anticoagulant	***
aripiprazole	Neuropsychiatric agent	***
avanafil	PDE5 inhibitor	***
bedaquiline	Antimycobacterial	***
betamethasone	Systemic corticosteroid	***
brexpiprazole	Neuropsychiatric agent	***
bosentan	Endothelin receptor antagonist	***
budesonide	Systemic corticosteroid	***
bupropion	Antidepressant	***

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

Drug	Drug Class	Interaction Code
bupirone	Sedative/hypnotic	***
carbamazepine	Anticonvulsant	XXX
cariprazine	Neuropsychiatric agent	***
ceritinib	Anticancer drug	***
ciclesonide	Systemic corticosteroid	***
cilostazol	Cardiovascular agent	***
clarithromycin	Anti-infective	***
clonazepam	Anticonvulsant	***
clorazepate	Sedative/hypnotic	***
clopidogrel	Cardiovascular agent	***
clozapine	Antipsychotic	***
colchicine	Anti-gout	XXX
cyclosporine	Immunosuppressant	***
dabigatran	Anticoagulants	***
darifenacin	Muscarinic receptor antagonist	***
dasabuvir	Hepatitis C direct acting antiviral	***
dasatinib	Anticancer drug	***
dexamethasone	Systemic corticosteroid	***
diazepam	Sedative/hypnotic	***
digoxin	Cardiac glycoside	***
dihydroergotamine	Ergot derivative	XXX
diltiazem	Calcium channel blocker	***
disopyramide	Antiarrhythmic	***
dronedarone	Antiarrhythmic	XXX
elbasvir/grazoprevir	Hepatitis C direct acting antiviral	***
eletriptan	Migraine medication	XXX
elexacaftor/tezacaftor/ivacaftor	Cystic fibrosis transmembrane conductance regulator potentiator	***
encorafenib	Anticancer drug	***
eplerenone	Cardiovascular agent	XXX
ergotamine	Ergot derivative	XXX
erythromycin	Anti-infective	***
estazolam	Sedative/hypnotic	***
everolimus	Immunosuppressant	***
felodipine	Calcium channel blocker	***
fentanyl	Narcotic analgesic	***
finerenone	Mineralocorticoid receptor antagonist	XXX
flecainide	Antiarrhythmic	XXX
flurazepam	Sedative/hypnotic	***
fluticasone	Systemic corticosteroid	***
flibanserin	Serotonin receptor 1A agonist/ serotonin receptor 2A antagonist	XXX

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

Drug	Drug Class	Interaction Code
glecaprevir/pibrentasvir	Hepatitis C direct acting antiviral	***
hydrocodone	Narcotic analgesic	***
ibrutinib	Anticancer drug	***
iloperidone	Neuropsychiatric agent	***
isavuconazonium sulfate	Antifungal	***
itraconazole	Antifungal	***
ivabradine	Cardiovascular agent	XXX
ivacaftor	Cystic fibrosis transmembrane conductance regulator potentiator	***
ivosidenib	Anticancer drug	***
ketoconazole	Antifungal	***
lidocaine (systemic)	Antiarrhythmic	***
lomitapide	Microsomal triglyceride transfer protein (MTTP) inhibitor	XXX
lumacaftor/ivacaftor	Cystic fibrosis transmembrane conductance regulator potentiator	XXX
lumateperone	Neuropsychiatric agent	***
lurasidone	Antipsychotic	XXX
meperidine	Narcotic analgesic	***
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	***
phenobarbital	Anticonvulsant	XXX
phenytoin	Anticonvulsant	XXX
pimavanserin	Neuropsychiatric agent	***
pimozide	Antipsychotic	XXX
primidone	Anticonvulsant	XXX
propafenone	Antiarrhythmic	XXX
quetiapine	Antipsychotic	***
quinidine	Antiarrhythmic	XXX
ranolazine	Antianginal	XXX
rifabutin	Antimycobacterial	***
rifampin	Antimycobacterial	XXX

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

Drug	Drug Class	Interaction Code
rifapentine	Antimycobacterial	XXX
rimegepant	Migraine medication	***
riociguat	sGC stimulator	***
rivaroxaban	Anticoagulant	***
salmeterol	Long-acting beta-adrenoceptor agonist	***
saxagliptin	DPP4 inhibitor	***
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	***
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	***
tofacitinib	JAK inhibitor	***
tolvaptan	Vasopressin receptor antagonist	XXX
trazodone	Antidepressant	***
triamcinolone	Systemic corticosteroid	***
triazolam	Sedative/hypnotic	XXX
ubrogepant	Migraine medication	XXX
upadacitinib	JAK inhibitor	***
vardenafil	PDE5 inhibitor	***
venetoclax	Anticancer drug	***
verapamil	Calcium channel blocker	***
vinblastine	Anticancer drug	***
vincristine	Anticancer drug	***
voclosporin	Immunosuppressant	XXX
vorapaxar	Cardiovascular agent	***
voriconazole	Antifungal	***
warfarin	Anticoagulant	***
zolpidem	Sedative/hypnotic	***

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

ADDITIONAL RESOURCES:

PAXLOVID - Fact Sheet for Healthcare Providers: <https://www.fda.gov/drugs/emergency-preparedness-drugs/emergency-use-authorizations-drugs-and-non-vaccine-biological-products>

Prescribing Information (Label/Package Insert) for Individual Drugs and for PAXLOVID (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>