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 ≥ 18 years OR ≥ 12 years of age and weighing at least 40 kg

❑ Has one or more risk factors for progression to severe COVID-19[1] (Healthcare providers should consider the benefit-risk for an individual patient.)

❑ Symptoms consistent with mild to moderate COVID-19[2]

❑ 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 ≤ 30 mL/min)
- Note that a dose reduction is required for patients with moderate renal impairment (eGFR ≥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

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[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 maraviroc[3], 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]

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[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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- ❑ <u>Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID</u>
    - ❑ 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: _____

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

Interaction Codes:

XXX	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 and the individual Prescribing Information for the drug.

The table below provides a listing of clinically significant drug interactions, including contraindicated drugs, <u>in addition to those listed under Concomitant Medications above</u> (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
avanafil	PDE5 inhibitor	***
bedaquiline	Antimycobacterial	***
betamethasone	Systemic corticosteroid	***
bosentan	Endothelin receptor antagonist	***
budesonide	Systemic corticosteroid	***
bupropion	Antidepressant	***
carbamazepine	Anticonvulsant	XXX
ceritinib	Anticancer drug	***

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Drug	Drug Class	Interaction Code
ciclesonide	Systemic corticosteroid	***
clarithromycin	Anti-infective	***
clopidogrel	Cardiovascular agent	***
clozapine	Antipsychotic	XXX
colchicine	Anti-gout	XXX
cyclosporine	Immunosuppressant	***
dabigatran	Anticoagulants	***
dasabuvir	Hepatitis C direct acting antiviral	***
dasatinib	Anticancer drug	***
dexamethasone	Systemic corticosteroid	***
digoxin	Cardiac glycoside	***
dihydroergotamine	Ergot derivative	XXX
diltiazem	Calcium channel blocker	***
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	***
everolimus	Immunosuppressant	***
felodipine	Calcium channel blocker	***
fentanyl	Narcotic analgesic	***
finerenone	Mineralocorticoid receptor antagonist	XXX
flecainide	Antiarrhythmic	XXX
fluticasone	Systemic corticosteroid	***
flibanserin	Serotonin receptor 1A agonist/ serotonin receptor 2A antagonist	XXX
glecaprevir/pibrentasvir	Hepatitis C direct acting antiviral	***
hydrocodone	Narcotic analgesic	***
ibrutinib	Anticancer drug	***
isavuconazonium sulfate	Antifungal	***
itraconazole	Antifungal	***
ivabradine	Cardiovascular agent	XXX
ivacaftor	Cystic fibrosis transmembrane conductance regulator potentiator	***
ivosidenib	Anticancer drug	***
ketoconazole	Antifungal	***

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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-/

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