This is an official
MS Health Alert Network (HAN) Alert

MESSAGE ID:	**MSHAN-20220708-00578-ALT (Health Alert)**
RECIPIENTS:	**All Physicians, Hospitals, ERs, ICPs, NPs, PAs, and Healthcare Providers – Statewide**
	Friday, July 8, 2022
SUBJECT:	**Mississippi Statewide Standing Order for Pharmacist-Administered Paxlovid July 8, 2022**

Rationale:

- Certain Mississippians are at high risk[1] for adverse outcomes from SARS-CoV-2 infection.
- Paxlovid (nirmatrelvir and ritonavir), treatment initiated early in the course of illness can markedly reduce the risk of adverse outcome among those at highest risk.
- On July 6, 2022, the U.S. Food and Drug Administration revised the Emergency Use Authorization (EUA)[2] for Paxlovid (nirmatrelvir and ritonavir), to allow state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid.

This order serves as a Standing Order for eligible patients with high-risk conditions[1] ≥12 years of age to receive Paxlovid (nirmatrelvir and ritonavir) administered by a pharmacist so long as this distribution conforms with the guidance in the FDA EUA[2]. ***This standing order covers standard dose Paxlovid and is not inclusive of renal dose Paxlovid.***

Special attention must be given to potential drug-drug interactions and underlying renal and liver function as directed by the guidance in the EUA. If these conditions cannot be met, patients should be referred to their primary physician or clinic for further guidance.
Patients who have tested positive for COVID-19 and are seeking to determine their eligibility for receiving Paxlovid at locations where prescribing by state-licensed pharmacists is available should bring the following information to ensure that the state-licensed pharmacist has sufficient information to determine their eligibility to receive Paxlovid:

- Electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work for the state-licensed pharmacist to review for kidney or liver problems. State-licensed pharmacists could also receive this information through a consult with the patient's health care provider.
- A list of all medications they are taking, including over-the-counter medications, so the state-licensed pharmacist can screen for drugs with potentially serious interactions with Paxlovid.

Under the limitations outlined in the authorization, <u>the state-licensed pharmacist should refer patients for clinical evaluation</u> with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.

- 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 current Fact Sheet for Healthcare Providers[3] or due to potential drug interactions for which recommended monitoring would not be feasible.

After completion of the accompanying checklist (starting on page 2), eligible patients may receive Paxlovid (300 mg nirmatrelvir (two 150 mg tablets) plus 100 mg ritonavir (one 100 mg tablet)) taken by mouth twice daily for 5 days. No refills.

Pharmacist Responsibilities:

- **Per the EUA, patients must receive the Patient and Caregiver Education Sheet[4] prior to dispensing Paxlovid.**
- **Patient consultation and counseling must be provided by a licensed pharmacist prior to dispensing Paxlovid.**

[1] Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals | CDC

[2] EUA 105 Pfizer Paxlovid LOA 07062022 (fda.gov)

[3] Fact Sheet for Healthcare Providers

[4] Paxlovid Patient FS 06282022 (fda.gov)

PAXLOVID Patient Eligibility Screening Checklist for Pharmacists

This checklist is intended as an aid to support clinical decision making and ensure compliance with the Mississippi State Department of Health PAXLOVID Standing Order for pharmacists.

Medical History	**(All questions must be answered "Yes" for patients to be eligible)**
☐Yes ☐No	Has the patient tested positive for SARS-CoV-2? (Includes confirmed positive home rapid SARS-CoV-2 test result)
☐Yes ☐No	Is the patient $\geq$18 years of age OR $\geq$12 years of age and $\geq$40 kg?
☐Yes ☐No	Symptom onset within last 5 days?
☐Yes ☐No	Symptoms consistent with mild to moderate COVID-19? (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell)
☐Yes ☐No	NOT requiring hospitalization due to severe or critical COVID-19 at treatment initiation?
☐Yes ☐No	Does the patient have adequate renal function that has been verified by the pharmacist? (eGFR > 60 mL/min; lab must be within the last 12 months)
☐Yes ☐No	No known or suspected severe hepatic impairment (Child-Pugh Class C)?
☐Yes ☐No	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.
☐Yes ☐No	Is the patient NOT currently pregnant or breastfeeding?
☐Yes ☐No	Does the patient have any of the following medical conditions / risk factors?

- 65 years of age or older
- Asthma
- Cancer
- Cerebrovascular disease
- Chronic lung disease
- Cystic Fibrosis
- Diabetes
- Heart conditions (e.g., heart failure, coronary artery disease, cardiomyopathies)
- HIV (human immunodeficiency virus)
- Mental health disorders (limited to mood disorders including depression as well as schizophrenia spectrum disorders
- Dementia
- Obese (BMI >30 kg/m^2) or Overweight (BMI >25 kg/m^2)
- Physical inactivity
- Smoking, current or former
- Sickle Cell Disease
- Substance Use Disorder
- Thalassemia
- Disabilities (see full list at https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html)

Concomitant Medications

☐ Do you have a complete and accurate medication list available?

☐ Is the patient on any of the following medications? If yes, do **NOT** prescribe PAXLOVID and refer patient to provider.

- Abemaciclib (VERZENIO)
- Alfuzosin (UROXATRAL)
- Aliskiren (TEKTURNA)
- Amiodarone (PACERONE)
- Amlodipine (NORVASC)
- Apalutamide (ERLEADA)
- Atazanavir (REYATAZ)
- Atorvastatin (LIPITOR)
- Bedaquiline (SIRTUO)
- Betamethasone (*All formulations*)
- Bictegravir/Emtricitabine/ Tenofovir (BIKTARVY)
- Bosentan (TRACLEER)
- Budesonide (*All formulations*)
- Carbamazepine
- Ceritinib (ZYKADIA)
- Ciclesonide (*All formulations*)
- Clarithromycin (BIAXIN)
- Clopidogrel (PLAVIX)
- Clozapine (CLOZARIL)
- Colchicine (COLCRYS; *if taking daily; does not include PRN use*)
- Cyclosporine
- Dabigatran (PRADAXA)
- Darunavir (PREZISTA)
- Dasatinib (SPRYCEL)
- Dexamethasone (*All formulations*)
- Digoxin
- Dihydroergotamine
- Diltiazem (CARDIZEM, TIAZAC)
- Dronedarone (MULTAQ)
- Efavirenz (SUSTIVA)
- Elbasvir/Grazoprevir (ZEPATIER)
- Glecaprevir/Pibrentasvir (MAVYRET)
- Elexacaftor/Tezacaftor/Ivacaftor (TRIKAFTA)
- Encorafenib (BRAFTOVI)

- Flecainide
- Flibanserin (ADDYI)
- Fluticasone (*All formulations*)
- Hydrocodone
- Ibrutinib (IMBRUVICA)
- Isavuconazonium sulfate (CRESEMBA)
- Itraconazole
- Ivabradine (CORLANOR)
- Ivacaftor (KALYDECO)
- Ivosidenib (TIBSOVO)
- Ketoconazole
- Lidocaine (*systemic*)
- Lomitapide (JUXTAPID)
- Lovastatin
- Lumacaftor/Ivacaftor (ORKAMBI)
- Lurasidone (LATUDA)
- Maraviroc (SELZENTRY)
- Methadone
- Methylergonovine (METHERGINE)
- Methylprednisolone (*All formulations*)
- Midazolam (VERSED)
- Mometasone (*All formulations*)
- Naloxegol (MOVANTIK)
- Neratinib (NERLYNX)
- Nevirapine
- Nicardipine (CARDENE)
- Nifedipine (ADALAT, PROCARDIA)

- Propafenone
- Quetiapine (SEROQUEL)
- Quinidine
- Ranolazine (RANEXA)
- Rifabutin (MYCOBUTIN)
- Rifampin
- Rifapentine (PRIFTIN)
- Rimegepant (NURTEC)
- Rivaroxaban (XARELTO)
- Rosuvastatin (CRESTOR)
- Salmeterol
- Sildenafil (REVATIO; *for Pulmonary Arterial HTN*)
- Silodosin (RAPAFLO)
- Simvastatin (ZOCOR)
- Sirolimus (RAPAMUNE)
- Sofosbuvir/Velpatasvir/ Voxilaprevir (VOSEVI)
- St. John's Wort
- Suvorexant (BELSOMRA)
- Tacrolimus (PROGRAF)
- Tadalafil (ADCIRCA; *for Pulmonary Arterial HTN*)
- Tamsulosin (FLOMAX)
- Tezacaftor/Ivacaftor (SYMDEKO)
- Ticagrelor (BRILINTA)
- Tipranavir (APTIVUS)
- Tolvaptan (JYNARQUE, SAMSCA)
- Trazodone (DESYREL)
- Triamcinolone (*All formulations*)
- Triazolam (HALCION)
- Venetoclax (VENCLEXTA)
- Verapamil (CALAN, VERELAN)
- Vinblastine
- Vincristine
- Voclosporin (LUPKYNIS)
- Vorapaxar (ZONTIVITY)

- Eplerenone (INSPRA)
- Ergotamine
- Erythromycin
- Everolimus (AFINITOR)
- Felodipine (PLENDIL)
- Fentanyl
- Finerenone (KERENDIA)

- Nilotinib (TASIGNA)
- Ombitasvir/Paritaprevir/ Ritonavir and Dasabuvir (VIEKIRA PAK)
- Oxycodone
- Pethidine
- Phenobarbital
- Phenytoin (DILANTIN, PHENYTEK)
- Pimozide
- Primidone (MYSOLINE)

- Voriconazole (VFEND)
- Warfarin (COUMADIN, JANTOVEN)
- Zidovudine (RETROVIR)

Concomitant Medications

A licensed pharmacist must counsel patient to avoid concomitant use of the below medications while taking PAXLOVID.

☐Yes ☐No   Is the patient taking a **PDE5 inhibitor** for erectile dysfunction? (avanafil, sildenafil, tadalafil, vardenafil)

- *If yes, PAXLOVID can be given if the PDE5 inhibitor can be held during the 5 days of therapy and restarted 3 days after completing PAXLOVID.*

☐Yes ☐No   Is the patient taking **colchicine (COLCRYS)** AS NEEDED (not as maintenance)?

- *If yes, PAXLOVID can be given if colchicine can be held during the 5 days of therapy.*
- *Do not prescribe PAXLOVID if the patient is taking colchicine as maintenance therapy*

☐Yes ☐No   Is the patient taking **eletriptan (RELPAX)**?

- *If yes, PAXLOVID can be given if eletriptan can be held during the 5 days of therapy.*

☐Yes ☐No   Is the patient taking **ubrogepant (UBRELVY)**?

- *If yes, PAXLOVID can be given if ubrogepant can be held during the 5 days of therapy.*

☐Yes ☐No   Is the patient on an **ethinyl estradiol**-containing contraceptive?

- *If yes, educate the patient that PAXLOVID may reduce the effectiveness of the contraceptive. Caution should be used during PAXLOVID treatment and until one menstrual cycle after stopping PAXLOVID.*
- *If yes, inform patient that irregular bleeding can occur.*

Patient Education

☐Yes ☐No   Did a licensed pharmacist provide a patient consultation as well as patient counseling?

☐Yes ☐No   Has the patient received the Patient and Caregiver Education Sheet?

Reporting and Recordkeeping
Healthcare providers must submit a report on all medication errors and ALL SERIOUS ADVERSE
EVENTS potentially related to Paxlovid. See EUA for instructions on reporting adverse events.
A copy of the standing order signed by the Mississippi State Health Officer must be maintained on
file and readily retrievable at each participating site.

For additional information, please refer to the PAXLOVID Fact Sheet
https://www.fda.gov/media/155050/download
Statement of Approval by the State Health Officer
The statewide standing order for Paxlovid has been approved for use by authorized healthcare
professionals from July 8, 2022 to July 31, 2022.

_____
State Health Officer
Mississippi State Department of Health

This the 8th day of July 2022.

Alerting Message Specification Settings

Originating Agency:	Mississippi State Department of Health
Alerting Program:	**MS Health Alert Network (MS HAN)**
Message Identifier:	MSHAN-20220708-00578-**ALT**
Program (HAN) Type:	**Health Alert**
Status (Type):	Actual ()
Message Type:	Alert
Reference:	MSHAN-00578
Severity:	Unknown
Acknowledgement:	No
Sensitive:	Not Sensitive
Message Expiration:	Undetermined
Urgency:	Undetermined
Delivery Time:	600 minutes

Definition of Alerting Vocabulary and Message Specification Settings

Originating Agency: A unique identifier for the agency originating the alert.

Alerting Program: The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

Message Identifier: A unique alert identifier that is generated upon alert activation (MSHAN-yyymmdd-hhmm-TTT (**ALT=Health Alert**, **ADV=Health Advisory**, **UPD=Health Update**, **MSG/INFO=Message/Info Service**).

Program (HAN) Type: Categories of Health Alert Messages**.**

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation; may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Health Info Service: Provides Message / Notification of general public health information; unlikely to require immediate action.

Status (Type):

	Actual:	Communication or alert refers to a live event
	Exercise:	Designated recipients must respond to the communication or alert
	Test:	Communication or alert is related to a technical, system test and should be disregarded

Message Type:

	Alert:	Indicates an original Alert
	Update:	Indicates prior alert has been Updated and/or superseded
	Cancel:	Indicates prior alert has been cancelled
	Error:	Indicates prior alert has been retracted

Reference: For a communication or alert with a Message Type of "Update" or "Cancel", this attribute contains the unique Message Identifier of the original communication or alert being updated or cancelled. "n/a" = Not Applicable.

Severity:

Extreme:	Extraordinary threat to life or property
Severe:	Significant threat to life or property
Moderate:	Possible threat to life or property
Minor:	Minimal threat to life or property
Unknown:	Unknown threat to life or property

Acknowledgement: Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required (Yes or No).

Sensitive:

Sensitive:	Indicates the alert contains sensitive content
Not Sensitive:	Indicates non-sensitive content

Message Expiration: Undetermined.

Urgency: Undetermined. Responsive action should be taken immediately.

Delivery Time: Indicates the timeframe for delivery of the alert (15, 60, 1440, 4320 minutes (.25, 1, 24, 72 hours)).