PAXLOVID (nirmatrelvir tablets; ritonavir tablets) - COVID-19 OUTPATIENT ORAL TREATMENT

Form must be completed in its entirety	
Site Name:	**Visit Date**(mm/dd/yyyy)**:**
Patient Name:	**FIN:**

EXCLUSION: PAXLOVID IS NOT AUTHORIZED FOR USE IN INDIVIDUALS:

- ☐ For use as prevention of COVID-19 (must be used as treatment of confirmed SARS-CoV-2 virus only)
- ☐ For patients hospitalized for the medical treatment of COVID-19
- ☐ Active liver disease
- ☐ Receiving dialysis or severe renal impairment
- ☐ Current or expected use of any medications or substances that are highly dependent on CYP3A4 for clearance or are strong inducers of CYP3A4
- ☐ Oxygen saturation of <92% on room air, or on their standard home oxygen supplementation for those who regularly receive chronic supplementary oxygen for an underlying lung condition
- ☐ Females that are pregnant, breastfeeding, or plan to become pregnant

INCLUSION: MUST MEET ALL OF THE FOLLOWING:

- ☐ 18 years of age and older
- ☐ Confirmed SARS-CoV-2 infection with symptom onset within 5 days
- ☐ Alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate
- ☐ High-risk for progression to severe COVID, including hospitalization or death

Criteria for Identifying High Risk Individuals: The following medical conditions or other factors may place patients at higher risk for progression to severe COVID-19:

- ☐ Older age (for example age ≥65 years of age)
- ☐ Obesity or being overweight (BMI >30)
- ☐ Chronic kidney disease
- ☐ Diabetes
- ☐ Immunosuppressive disease or immunosuppressive treatment**
- ☐ Cardiovascular disease (including congenital heart disease)
- ☐ Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- ☐ Sickle cell disease
- ☐ Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)

Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))

eGFR*	PAXLOVID Dose
Greater than 60 mL/min (*normal renal function or mild renal impairment*)	300 mg nirmatrelvir with 100 mg ritonavir, taken twice daily for 5 days
≥30 to <60 mL/min (*moderate renal impairment*)	150 mg nirmatrelvir with 100 mg ritonavir, taken twice daily for 5 days
<30 mL/min (*severe renal impairment*)	PAXLOVID is not recommended (the appropriate dose has not been determined).

*eGFR=estimated glomerular filtration rate based on the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) formula

PAXLOVID is **CONTRAINDICATED** with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with **serious and/or life-threatening reactions**

- Alpha1-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, piroxicam, propoxyphene
- Antianginal: ranolazine • Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

PAXLOVID is **CONTRAINDICATED** with drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. PAXLOVID cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer [see Drug Interactions (7.3)]:

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John's Wort (hypericum perforatum)

☐ I attest that the patient meets the requirements for treatment as put forth by the emergency use authorization (EUA). I have discussed with the patient/caregiver potential alternatives to this medication for treating COVID-19. The patient/caregiver has been provided the "Fact Sheet for Patients, Parents, and Caregivers". I have informed the patient that this medication is available as an unapproved drug that is authorized for use under an EUA.

Provider Signature:_____ Date (mm/dd/yyyy): _____

Patient Name:	Visit Date(mm/dd/yyyy):
Phone Number:	Patient Date of Birth:
Patient Address:	

PAXLOVID ORDER SHEET

PLEASE CHOOSE CORRECT REGIMEN BASED ON RENAL FUNCTION	
☐	**Patients with <u>normal renal function</u> (eGFR>60 mL/min):** ➢ **Paxlovid (300mg nirmatrelvir with 100mg ritonavir) BID for 5 days** **Quantity: 5 day supply**
☐	**Patients with <u>moderate renal impairment</u> (eGFR >30 to <60 mL/min):** ➢ **Paxlovid (150mg nirmatrelvir with 100mg ritonavir) BID for 5 days** **Quantity: 5 day supply**

*****FAX COMPLETED PACKET TO MEMORIAL OUTPATIENT PHARMACY AT <u>(228) 865-3618</u>*****

Outpatient pharmacy will contact patient to coordinate pick up.

I attest that the patient meets the requirements for treatment as put forth by the emergency use authorization (EUA) for PAXLOVID. I have discussed with the patient/caregiver potential alternatives to this medication for treating COVID-19. The patient/caregiver has been provided the "Fact Sheet for Patients, Parents, and Caregivers". I have informed the patient that this medication is available as an unapproved drug that is authorized for use under an EUA.

Name of person preparing order if not the provider listed below:

Direct contact number:

_____ _____

Physician Signature

Date/Time

_____ _____

Physician Printed Name

_____

1360A

CONSENT FOR EMERGENCY USE AUTHORIZATION (EUA) PAXLOVID

I hereby authorize, affirm and acknowledge my consent for emergency use authorization (EAU) of paxlovid and certify that my physician and I have discussed the risks, benefits, complications and alternative treatments related to this procedure.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization to permit the emergency use of the unapproved product paxlovid for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

There is limited clinical data available for paxlovid. Serious and unexpected adverse events may occur that have not been previously reported with paxlovid use.

Do not take PAXLOVID if:

- You are allergic to nirmatrelvir, ritonavir, or any of the ingredients in paxlovid
- You are taking any of the following medicines: alfuzosin, pethidine, piroxicam, propoxyphene, ranolazine, amiodarone, dronedarone, flecainide, propafenone, quinidine, colchicine, lurasidone, pimozide, clozapine, dihydroergotamine, ergotamine, methylergonovine, lovastatin, simvastatin, sildenafil (Revatio®) for pulmonary arterial hypertension (PAH), triazolam, oral midazolam, apalutamide, carbamazepine, phenobarbital, phenytoin, rifampin, St. John's Wort (hypericum perforatum)

Possible Side Effects: liver problems (loss of appetite, yellowing of skin and whites of eyes, dark-colored urine, pale colored stools, itchy skin, or stomach pain), resistance to HIV medicines, altered sense of taste, diarrhea, high blood pressure, and muscle pain.

- **Additional adverse events associated with the drug may become apparent with more widespread use** – paxlovid is still being studied, so it is possible that all of the risks are not known at this time. It is recommended that you use effective barrier contraception or do not have sexual activity while taking paxlovid.

I was given the "Fact Sheet for Patients, Parents and Caregivers," voluntarily accept all risks associated with use of paxlovid, and assume full responsibility for any risk of loss, damage, illness, or personal injury resulting from use of paxlovid.

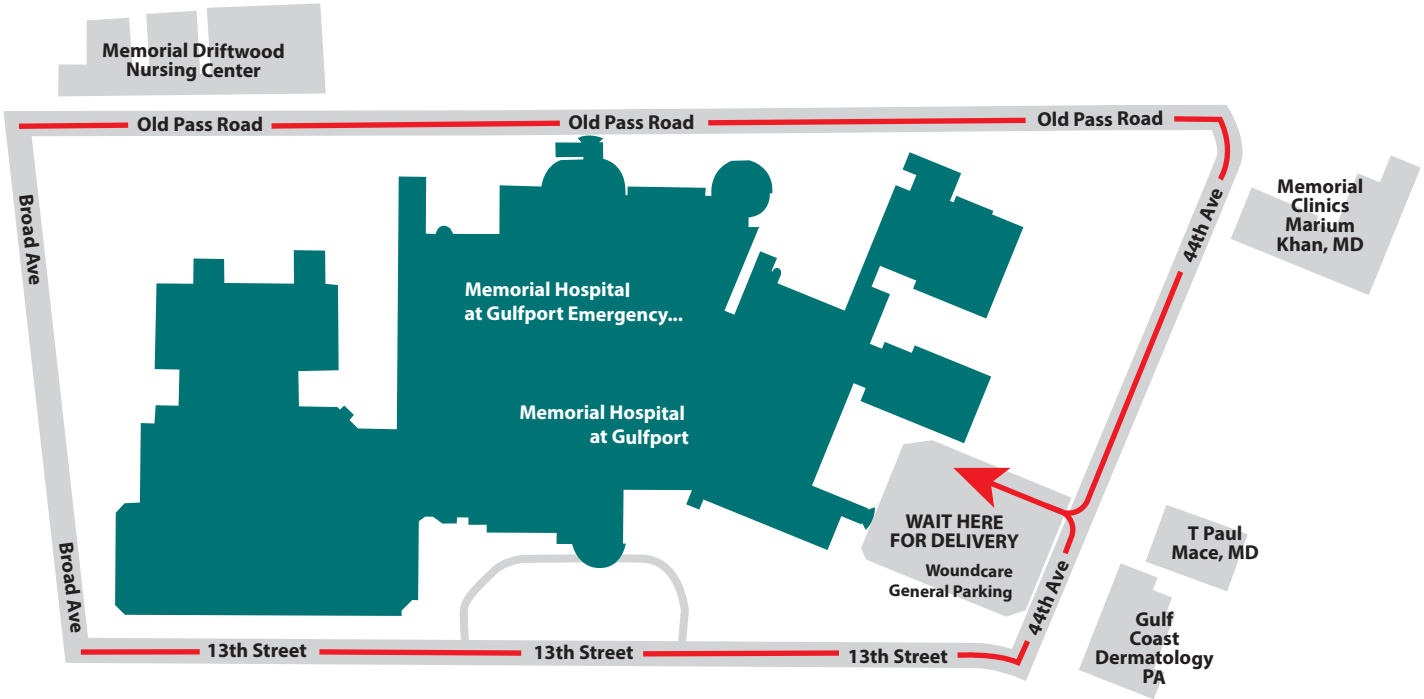
Patient signature:_____ Date:_____Time:_____
OR person legally permitted to sign

Physician signature:_____ Date:_____ Time:_____

Witness signature: _____ Date: _____ Time: _____

TEMPORARY COVID MEDICATION PICKUP LOCATION

Call (228) 865-3525 to schedule a pickup time
Monday - Friday 8 a.m. - 5 p.m.



Upon arrival, call (228) 865-3525 for delivery to curbside in the *wound care parking lot East Tower Entrance (green awning)*

Memorial

4500 13TH STREET | GULFPORT, MISSISSIPPI 39501

FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF PAXLOVID FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with PAXLOVID for the treatment of mild-to-moderate coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. This Fact Sheet contains information to help you understand the risks and benefits of taking the PAXLOVID you have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make PAXLOVID available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). PAXLOVID is not an FDA-approved medicine in the United States. Read this Fact Sheet for information about PAXLOVID. Talk to your healthcare provider about your options or if you have any questions. It is your choice to take PAXLOVID.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild-to-severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

What is PAXLOVID?

PAXLOVID is an investigational medicine used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (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. PAXLOVID is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19.

The FDA has authorized the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with a positive test for the virus that causes COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA.

What should I tell my healthcare provider before I take PAXLOVID?

Tell your healthcare provider if you:

- Have any allergies
- Have liver or kidney disease
- Are pregnant or plan to become pregnant
- Are breastfeeding a child
- Have any serious illnesses

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with PAXLOVID and may cause serious side effects. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

You can ask your healthcare provider or pharmacist for a list of medicines that interact with PAXLOVID. **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take PAXLOVID with other medicines.

Tell your healthcare provider if you are taking combined hormonal contraceptive. PAXLOVID may affect how your birth control pills work. Females who are able to become pregnant should use another effective alternative form of contraception or an additional barrier method of contraception. Talk to your healthcare provider if you have any questions about contraceptive methods that might be right for you.

How do I take PAXLOVID?

- PAXLOVID consists of 2 medicines: nirmatrelvir and ritonavir.
    - Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth 2 times each day (in the morning and in the evening) for 5 days. **For each dose, take all 3 tablets at the same time.**
    - **If you have kidney disease, talk to your healthcare provider. You may need a different dose.**
- Swallow the tablets whole. Do not chew, break, or crush the tablets.
- Take PAXLOVID with or without food.
- Do not stop taking PAXLOVID without talking to your healthcare provider, even if you feel better.
- If you miss a dose of PAXLOVID within 8 hours of the time it is usually taken, take it as soon as you remember. If you miss a dose by more than 8 hours, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of PAXLOVID at the same time.
- If you take too much PAXLOVID, call your healthcare provider or go to the nearest hospital emergency room right away.
- If you are taking a ritonavir- or cobicistat-containing medicine to treat hepatitis C or Human Immunodeficiency Virus (HIV), you should continue to take your medicine as prescribed by your healthcare provider.

Talk to your healthcare provider if you do not feel better or if you feel worse after 5 days.

Who should generally not take PAXLOVID?

Do not take PAXLOVID if:

- You are allergic to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID.
- You are taking any of the following medicines:
    - Alfuzosin
    - Pethidine, piroxicam, propoxyphene
    - Ranolazine
    - Amiodarone, dronedarone, flecainide, propafenone, quinidine
    - Colchicine
    - Lurasidone, pimozide, clozapine
    - Dihydroergotamine, ergotamine, methylergonovine
    - Lovastatin, simvastatin
    - Sildenafil (Revatio®) for pulmonary arterial hypertension (PAH)
    - Triazolam, oral midazolam
    - Apalutamide
    - Carbamazepine, phenobarbital, phenytoin
    - Rifampin
    - St. John's Wort (*hypericum perforatum*)

Taking PAXLOVID with these medicines may cause serious or life-threatening side effects or affect how PAXLOVID works.

These are not the only medicines that may cause serious side effects if taken with PAXLOVID. PAXLOVID may increase or decrease the levels of multiple other medicines. It is very important to tell your healthcare provider about all of the medicines you are taking because additional laboratory tests or changes in the dose of your other medicines may be necessary while you are taking PAXLOVID. Your healthcare provider may also tell you about specific symptoms to watch out for that may indicate that you need to stop or decrease the dose of some of your other medicines.

What are the important possible side effects of PAXLOVID?

Possible side effects of PAXLOVID are:

- **Liver Problems.** Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems: loss of appetite, yellowing of your skin and the whites of eyes (jaundice), dark-colored urine, pale colored stools and itchy skin, stomach area (abdominal) pain.
- **Resistance to HIV Medicines**. If you have untreated HIV infection, PAXLOVID may lead to some HIV medicines not working as well in the future.

- **Other possible side effects include:**
  - altered sense of taste
  - diarrhea
  - high blood pressure
  - muscle aches

These are not all the possible side effects of PAXLOVID. Not many people have taken PAXLOVID. Serious and unexpected side effects may happen. PAXLOVID is still being studied, so it is possible that all of the risks are not known at this time.

What other treatment choices are there?
Like PAXLOVID, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with PAXLOVID. Should you decide not to receive it or for your child not to receive it, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is no experience treating pregnant women or breastfeeding mothers with PAXLOVID. For a mother and unborn baby, the benefit of taking PAXLOVID may be greater than the risk from the treatment. If you are pregnant, discuss your options and specific situation with your healthcare provider.

It is recommended that you use effective barrier contraception or do not have sexual activity while taking PAXLOVID.

If you are breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with PAXLOVID?
Contact your healthcare provider if you have any side effects that bother you or do not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

How should I store PAXLOVID?
Store PAXLOVID tablets at room temperature, between 68°F to 77°F (20°C to 25°C).

How can I learn more about COVID-19?
- Ask your healthcare provider.
- Visit https://www.cdc.gov/COVID19.
- Contact your local or state public health department.

What is an Emergency Use Authorization (EUA)?
The United States FDA has made PAXLOVID available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (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, has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved, and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for PAXLOVID is in effect for the duration of the COVID-19 declaration justifying emergency use of this product, unless terminated or revoked (after which the products may no longer be used under the EUA).

Additional Information
For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.COVID19oralRx.com	1-877-219-7225 (1-877-C19-PACK)

www.pfizermedinfo.com or call 1-800-438-1985 for more information.

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