CONSENT FOR COVID-19 TREATMENT: Nirmatrelvir and Ritonavir (PAXLOVID)

Your medical provider has recommended you receive two drugs called nirmatrelvir and ritonavir also referred to as PAXLOVID. You have the option to receive these medications which are tablets taken by mouth. Before you decide whether you would like to receive these medications, your medical provider would like you to review this information. If you decide that you would like to receive this medication, you will be asked to sign this form. A copy of this form and an FDA approved fact sheet will be given to you for your reference.

As your medical provider has discussed with you, you have been diagnosed with COVID-19 (SARS-CoV-2). At present time, there are few Food and Drug Administration (FDA) approved, or clinically proven therapies for the treatment of COVID-19. As new clinical data emerges, local treatment guidelines are being developed. Local treatment guidelines will continue to be updated as new information becomes available.

BACKGROUND

PAXLOVID is an investigational medicine used to treatment mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization and 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 emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 disease under an Emergency Use Authorization (EUA). For more information about EUA, see “What is an Emergency Use Authorization (EUA)?” section of the Fact Sheet For Patients, Parents and Caregivers that you have received. Clinical trials are ongoing to study the safety and efficacy of PAXLOVID.

PAXLOVID consists of two medicines: nirmatrelvir and ritonavir that are taken together at the same time by mouth two times each day (in the morning and evening) for five days.

POSSIBLE BENEFITS OF PAXLOVID

It is possible that PAXLOVID may help to control your symptoms, slow or stop the growth of the virus, shorten the duration or lessen the severity of the illness in you. However there is the possibility that this medicine will be of NO directed medical benefit to you. Your condition may get worse.

POSSIBLE RISKS AND SIDE EFFECTS OF PAXLOVID

It is possible that PAXLOVID may not improve your symptoms, slow or stop the growth of the virus, shorten the duration of your illness or lessen the severity of your illness. It is possible that PAXLOVID will interfere with your ability to improve, hasten damage to the lungs or other organs, and shorten your life.

Liver Problems. Tell your medical provider right away if you get any of these signs and symptoms of liver problems: loss of appetite, yellowing of your skin and the whites of your eyes (jaundice), dark-colored urine, pale colored stools and itchy skin, or pain your stomach area (abdominal pain).

Resistance to Human Immunodeficiency Virus (HIV) Medicines. If you have untreated HIV infection, PAXLOVID may lead to some HIV medications not working as well in the future.

Other possible side effects include: altered sense of taste, diarrhea, high blood pressure, and 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.

Continued on page 2 ⇨

Continued from page 1

Drug Interactions. Some medicines may interact with PAXLOVID and may cause serious side effects. Your medical provider or pharmacist will ask you to provide a list of all of your medicines before prescribing or dispensing PAXLOVID.

OTHER TREATMENT CHOICES

Like PAXLOVID, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Talk to your medical provider about other treatments for COVID-19. It is your choice 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.

CERTIFICATION AND SIGNATURES

I have read this informed consent form and all of my questions have been answered to my satisfaction by my medical provider. I understand that I have the right to refuse to take this medication for any reason. If I choose not to take this medication, this decision will not otherwise affect my status as a patient. I voluntarily consent to take these medications by mouth as discussed with my medical provider and as described in this consent form.

CONSENT

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies for COVID-19 treatment. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization.

DATE: _____ **TIME:** _____
(Applicable for patient and witness as they are done at the same time)

_____
Signature of the Patient

If the patient is unable to personally sign, please indicate reason:
❑ Incapacitated ❑ Minor child ❑_____

_____ _____
Signature of Parent, Personal Representative or Medical Durable Power of Attorney

Printed Name of Parent, Personal Representative or Medical Durable Power of Attorney

_____ _____
Witness of Signature

Printed Name of Witness

If sign language or limited English proficiency interpretive services were utilized:

_____ _____
Interpreter Printed Name

Interpreter Identification Number

PATIENT IDENTIFICATION:

OUTPATIENT COVID TREATMENT ORDERS: Nirmatrelvir Co-Packaged with Ritonavir (PAXLOVID)

Name:_____ DOB:_____

Date of symptom onset:_____Medication Allergies: _____

Height: _____ inches Weight:_____kg Patient Phone #:_____

Emergency use of nirmatrelvir co-packaged with ritonavir (PAXLOVID) is authorized for treatment of mild-to-moderate COVID-19 in adults and pediatric patients (age 12 and older weighing at least 40 kg) with positive direct SARS-CoV-2 viral testing who are at high risk of progression to severe COVID-19, including hospitalization or death. Please mark the criteria that places this patient in the high risk category. Failure to indicate eligibility criteria may result in treatment delay or denial.

____ Age $\geq$ 65 years
____ Obesity or being overweight (BMI >25 mg/m2, or if age 12-17, BMI $\geq$ 85th percentile for age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
____ Pregnancy
____ Diabetes
____ Chronic kidney disease
____ Immunosuppressive disease or immunosuppressive treatment
____ Cardiovascular disease (including congenital heart disease) or hypertension
____ Chronic lung disease (COPD, moderate to severe asthma, interstitial lung disease, CF, pulmonary hypertension)
____ Sickle cell disease
____ Neurodevelopment disorders
____ Dependence on medical-related technology (tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19])

***** Note: Patient should be symptomatic and within 5 days of symptom onset*****

This therapy is NOT authorized for use in patients who are hospitalized due to COVID-19, for pre-exposure prophylaxis or post-exposure prophylaxis for prevention of COVID-19, or for use longer than 5 consecutive days.

OUTPATIENT COVID TREATMENT:

_X_ Pharmacist to review patient's current medications including OTC medications and herbal supplements to screen for relevant drug-drug interactions with PAXLOVID using NIH guidance available at:

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/

_X_ Pharmacist to contact provider regarding relevant drug-drug interactions and appropriate management

___ eGFR $\geq$ 60 mL/min: Nirmatrelvir 300 mg (2 tablets) + ritonavir 100 (1 tablet) by mouth twice daily for 5 days

___ eGFR 30-60 mL/min: Nirmatrelvir 150 mg (1 tablet) + ritonavir 100 mg (1 tablet) by mouth twice daily for 5 days

PAXLOVID is not recommended in patients with severe renal impairment (eGFR < 30 mL/min) or severe hepatic impairment (Child-Pugh Class C).

_X_ Pharmacist may substitute an alternative COVID-19 therapy if the patient is not a candidate for PAXLOVID due to drug interactions, renal function, or onset of symptoms.

My signature indicates that I have discussed the risks and benefits of this therapy and a signed informed consent is attached.

Provider Sign:_____(Print):_____Date:_____Time:_____

Provider Phone Number: _____

Please fax a copy of the completed order and the signed consent form to 406-495-6809

PATIENT IDENTIFICATION:

St. Peter's Health
2475 Broadway • Helena, MT 59601 (406) 442-2480

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