Yukon-Kuskokwim HEALTH CORPORATION

Clinical Guideline

Emergency Use of Paxlovid

Ritonavir-Boosted Nirmatrelvir (brand name Paxlovid)

- Mechanism: Nirmatrelvir is a protease inhibitor; ritonavir is a cytochrome P450 3A4 inhibitor that increases nirmatrelvir concentrations.
- Regimen: Paxlovid is packaged with nirmatrelvir 150 mg x2 and ritonavir 100 mg. Take all three pills (nirmatrelvir 300 mg and ritonavir 100 mg) PO twice daily for five days. Initiate within five days of symptom onset.
- Main concerns: Significant drug-drug interactions.

A pharmacist must be involved with all Paxlovid prescriptions.

Village and SRC Prescriptions

If considering administration in a village or SRC, either provider or health aide to contact pharmacist:
- Weekdays: Send message via Tiger Connect to "Village Ops Pharmacist."
- Weekends: Send message via Tiger Connect to "Inpatient Pharmacy on Call."

ED or Outpatient Clinic Prescriptions

If considering prescribing to a patient in the ED or Outpatient Clinic, provider to contact pharmacist:
- Business hours: Send prescription to pharmacy as usual.
- Weekends, 7 am to 7 pm: Send message via Tiger Connect to "Inpatient Pharmacy on Call."
- Overnight: Send email to InpatientPharmacists@ykhc.org with the patient's name, MRN, and a reliable phone number. Tell the patient that a pharmacist will call in the morning to discuss the medication and logistics.

Criteria:
- Age ≥12 years and weight ≥40 kg
- Lab-confirmed COVID-19
- Mild to moderate disease in the outpatient setting
- High risk of progressing to severe illness.
- No contraindications (see box).

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- Document using "..Paxlovid" autotext and comment on need for labs. May place this in an Alert Note and complete full documentation later.
- Consult a pharmacist. (See red box for details.)

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Pharmacist reviews chart and determines:
- If labs are necessary (see box).
- If medication list needs modification during course of treatment.
- If renal dosing is needed.

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Pharmacist contacts health aide (for village patients) or provider (for SRC/Outpatient/ED patients) and makes plan for labs and dose, as appropriate.

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Counsel patient/caregiver and document per requirements in box.

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- Prescribe Paxlovid as soon as possible after positive COVID test and within five days of symptom onset.
- Patient should take nirmatrelvir 300 mg (two 150 mg tabs) and ritonavir 100 mg PO twice daily for five days unless renal adjustment is needed.

Note

- Ritonavir can have significant **drug-drug interactions**. These interactions are increased with renal or hepatic insufficiency.
- Pharmacist involvement is essential in making adjustments to chronic medications and creating a patient-specific, tailored plan.

Indications for Labwork (CMP)

- Age ≥65 years.
- Hypertension, diabetes, or CVD
- Other chronic viral illness (HIV, Hepatitis C)
- Malignancy, autoimmune diseases, nephrolithiasis, or recurrent UTIs
- Chronic use of nephrotoxic medications
- Family history or past history of CKD
- Clinical judgment.

(May defer If checked in the last 12 months and no suspicion for worsening renal or hepatic impairment in that time.)

Adverse Reactions

In the clinical studies quoted in the EUA, the following adverse events were reported: dysgeusia, diarrhea, hypertension, and myalgia.

Contraindications

- Paxlovid is NOT authorized for use in patients who are hospitalized, requiring supplemental oxygen, or requiring more than their baseline supplemental oxygen flow rates due to COVID.
- Do not give to any patient with known hypersensitivity to any ingredient of Paxlovid.
- Review patient's medications (including herbal supplements) for drug-drug interactions, summarized at the **NIH COVID Treatment Guidelines** website and on pages 9-15 of the **EUA Fact Sheet for Health Care Providers**.

Special Populations

- Pregnancy & Breastfeeding: There are no available data in these populations to use to make a recommendation.
- Renal Impairment:
  - Moderate (eGFR ≥30 to <60 mL/min): change dose to nirmatrelvir 150 mg (one tab) and ritonavir 100 mg (one tab)
  - Severe (eGFR <30 mL/min): not recommended
- Hepatic Impairment: not recommended if **Child-Pugh Score** Class C.

Documentation Requirements for Paxlovid

Communicate and document the following in the medical record:
- **Fact Sheet for Patients and Parents/Caregivers** given to patient/caregiver.
- Inform patient/caregiver of alternatives to receiving Paxlovid. See **clinicaltrials.gov** for emerging data.
- Inform patient/caregiver that Paxlovid is an unapproved drug that is authorized for use under Emergency Use Authorization.

Reporting of Adverse Events

The prescribing health care provider is responsible for mandatory reporting of all medication errors and adverse events potentially related to Paxlovid. Reports must be made within seven days of the event.
Serious adverse events include: death; life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant incapacity or substantial disruption of the ability to conduct normal life function; congenital anomaly/birth defect; or medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

Submit report to FDA MedWatch by completing the online form **here**.
The report should include "use of Paxlovid under Emergency Use Authorization (EUA)" in the "Describe Event" section.

See the **FDA MedWatch program** for more information.

Resource: Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of PAXLOVID.
Updated September 2022. Click **here** for source.

This guideline is designed for the general use of most patients but may need to be adapted to meet the special needs of a specific patient as determined by the medical practitioner.
Approved by Clinical Guideline Committee 12/9/22.
If comments about this guideline, please contact Leslie_Herrmann@ykhc.org.