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.

If considering administration in a village, a pharmacist MUST be consulted.
- Weekdays: Send message via Tiger Connect to "Village Ops Pharmacist."
- Weekends: Send message via Tiger Connect to "Inpatient Pharmacy."

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.

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No contraindications (see box)
AND
No anticipated **drug-drug interactions** (see box)

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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.

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 April 14, 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 6/6/22.
If comments about this guideline, please contact Leslie_Herrmann@ykhc.org.