The U.S. Food and Drug Administration (FDA) recently revised the Emergency Use Authorization (EUA) for nirmatrelvir with ritonavir to allow state-licensed pharmacists to prescribe the medication to eligible patients under certain conditions. Details can be found in the Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid™. This tip sheet is intended to provide general information for organizations to consider when planning and implementing pharmacist prescribing of nirmatrelvir with ritonavir.

PATIENT CARE ENVIRONMENT

- Appropriate protection during patient evaluation:
  - Consider protections for pharmacy staff and others in proximity to a patient with a positive SARS-CoV-2 test.
  - Use remote methods of evaluation when possible (e.g., telephone, telehealth, drive-through).
  - Ensure appropriate masking and other personal protective equipment (PPE) if in-person evaluation is necessary.

PATIENT EVALUATION

The following information is required for evaluation and prescribing nirmatrelvir with ritonavir. The FDA has also published a Patient Eligibility Screening Checklist Tool for Prescribers that organizations may find helpful for pharmacist evaluation of individual patients.

- Positive direct SARS-CoV-2 test result:
  - Nucleic acid amplification tests (e.g., PCR) and home antigen tests are acceptable.
    - Patient reporting of home antigen tests is also acceptable.
    - Antibody tests are not indicative of active SARS-CoV-2 infection and are not acceptable.
  - Testing does not need to be performed by the evaluating prescriber.

- Age, weight:
  - Patients must be 12 years of age or older and weigh 40 kg or more

- Symptoms of mild-to-moderate COVID-19:
  - Pharmacists must evaluate patients for mild-to-moderate symptoms of COVID-19 to determine eligibility for nirmatrelvir with ritonavir.
  - Patients with severe respiratory symptoms or difficulty breathing should be referred to urgent care or an emergency department.

- Risk of progression to severe COVID-19:
  - Pharmacists must evaluate patients for risk factors for progression to severe COVID-19 to determine eligibility for nirmatrelvir with ritonavir.
CONSIDERATIONS FOR PHARMACIST PRESCRIBING NIRMATRELVIR WITH RITONAVIR (PAXLOVID™)

- Medical and Allergy History
  - Pharmacists must determine if patients have any contraindications to nirmatrelvir with ritonavir, including hypersensitivity to the medications or components, Child-Pugh class C liver disease, or estimated GFR below 30 mL/min.
  - Pharmacists must have sufficient information to evaluate renal and hepatic function. Examples include:
    - Laboratory values within the past 12 months.
    - Printed or electronic medical records with a medical history or problem list within the past 12 months.
      - The absence of renal or hepatic insufficiency in a medical history or problem list is sufficient for evaluating renal and hepatic function.
    - Communication with the patient’s primary care provider.
    - Interviewing the patient about a past medical history of liver or renal disease is not sufficient for pharmacist evaluation of their eligibility for nirmatrelvir with ritonavir.
  - Pharmacists may prescribe the renally adjusted dose of nirmatrelvir with ritonavir if necessary.

- Comprehensive Medication List
  - Pharmacists must review a comprehensive medication list, including over-the-counter medications and dietary supplements, to check for drug-drug interactions with ritonavir.
    - The medication list from a printed or electronic medical record may be used, although pharmacists should ensure the list is complete and current.
    - Interviewing the patient, directly, to collect a comprehensive medication list is also acceptable.
  - The comprehensive medication list must be reviewed for interactions with ritonavir:
    - FDA Patient Eligibility Screening Checklist Tool for Prescribers
    - University of Liverpool COVID-19 Drug Interaction Checker
  - Drug-drug interactions that can be mitigated similar to other drug-drug interactions identified through the course of normal pharmacist medication order (prescription) review.

- If the patient is not eligible for pharmacist-prescribed nirmatrelvir with ritonavir because of insufficient documentation, the patient should be referred to another practitioner who can prescribe Paxlovid.
- If the patient is not eligible for nirmatrelvir with ritonavir due to drug-drug interactions that cannot be mitigated or due to other contraindications, the patient should be referred to another practitioner who can prescribe a different COVID-19 treatment.

PRESCRIBING AND DISPENSING

- If the required information is available and the patient meets eligibility criteria, the pharmacist may prescribe the standard dose or renally adjusted dose of nirmatrelvir with ritonavir.
- A copy of the Fact Sheet for Patients, Parents, and Caregivers must be provided with nirmatrelvir with ritonavir.
- Prescribing pharmacists are responsible for reporting serious adverse events and medication errors to FDA MedWatch within seven calendar days from their awareness of the event. Prescribing pharmacists are also asked to submit a copy of the report to Pfizer Safety Reporting.