Prescriber Checklist Tool

PAXLOVID™

UTAH DEPARTMENT OF HEALTH

Updated 2/8/2022

Patient eligibility

The FDA has issued an emergency use authorization (EUA) for ritonavir-boosted nirmatrelvir (PAXLOVID) for the **treatment** of COVID-19 in the following individuals:

- ❑ Testing positive for SARS-CoV-2, and
- ❑ Aged ≥12 years and weighing at least 40 kg, and
- ❑ Having symptoms consistent with mild to moderate COVID-19, and
- ❑ Having symptom onset within 5 days*, and
- ❑ At high risk for progression to severe COVID-19**, and
- ❑ Not hospitalized due to COVID-19.

Information before administration

Information to review prior to a patient receiving PAXLOVID under EUA

- ❑ Healthcare practitioners must communicate to the patient and/or caregiver information consistent with the Fact Sheet For Patients, Parents, and Caregivers and provide them with a copy of such Fact Sheet prior to administration of PAXLOVID.
- ❑ Important prescribing instructions:
  - Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together twice daily for 5 days.
- ❑ Dosing information in patients with renal impairment:
  - No dosage adjustment is needed in patients with mild renal impairment (eGFR ≥60 to <90 ml/min).
  - Dose in moderate renal impairment (eGFR ≥30 to <60 ml/min): reduce regular dose to 150 mg of nirmatrelvir (one 150 mg tablet) with 100 mg of ritonavir (one 100 mg tablet) taken together twice daily for 5 days.
  - PAXLOVID is not recommended in patients with severe renal impairment (eGFR <30 ml/ min).
- ❑ Use in patients with hepatic impairment:
  - No dosage adjustment needed in mild to moderate hepatic impairment; not used in severe hepatic impairment.

Drug interactions for review

Information regarding drug interactions to review prior to a patient receiving PAXLOVID

- ❑ Important drug interactions with PAXLOVID:
  - Ritonavir is an inhibitor of CYP3A4.
  - Ritonavir and nirmatrelvir are CYP3A4 substrates, thus, drugs that induce CYP3A4 may decrease the therapeutic effect of PAXLOVID.
  - PAXLOVID is contraindicated with drugs that are highly dependent on CYP3A4 (Please refer to sections 4 and 7, and table 1 of the PAXLOVID Fact Sheet for Healthcare Providers for important drug interaction information).
- ❑ Hormonal contraceptives:
  - Ritonavir may reduce the efficacy of combined oral contraceptives (ethynyl estradiol); patients on combined hormonal contraceptives should use an effective alternative contraceptive method or an additional barrier method, or not have sexual activity during treatment with PAXLOVID.
- ❑ No dosage adjustment is required when co-administered with other products containing ritonavir or cobicistat.
- ❑ Patients on HIV or HCV regimens containing ritonavir or cobicistat should continue their treatment as indicated.
- ❑ Risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1.

Important notice

The prescribing healthcare provider and/or designee must report all medication errors and serious adverse events potentially related to PAXLOVID within 7 calendar days from the healthcare provider's awareness of the event to FDA MedWatch.

* Prescriber is encouraged to include a note in the prescription alerting the dispensing pharmacist of the "prescription fill by date," which should be within 5 days from symptom onset to comply with the patient eligibility criteria under the EUA.

** Per the EUA, high-risk patients had one or more of the following: diabetes, overweight (BM1 >25), chronic lung disease (including asthma), chronic kidney disease, current smoker, immunosuppressive disease or immunosuppressive treatment, cardiovascular disease, hypertension, sickle cell disease, neurodevelopmental disorders, active cancer, medically-related technological dependence, or 60 years of age and older regardless of comorbidities.