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newsletter to promote pharmacy and drug law compliance

COVID-19 Update — Paxlovid Authorization

As the coronavirus disease 2019 (COVID-19) continues to affect patients, pharmacists are increasingly being utilized for their expertise and accessibility. On July 6, 2022, Food and Drug Administration (FDA) revised the emergency use authorization (EUA) for Paxlovid™ to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, only with strict compliance of the requirements set forth in the authorization to ensure appropriate patient assessment and prescribing.

Based on the totality of scientific evidence available to FDA, the agency believes that Paxlovid may be effective for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years and older weighing at least 40 kg) with a positive COVID-19 test, and who are at risk of developing severe COVID-19 to include hospitalization or death. FDA has authorized the use of Paxlovid under these conditions when the known and potential benefits of Paxlovid outweigh the known or potential risks of use. The EUA in its entirety is available on the Alabama State Board of Pharmacy website, and it is important that the entire EUA is read and understood.

The revised EUA authorizes state-licensed pharmacists to prescribe Paxlovid subject to the following conditions:

- Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and
- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient

relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

Under the limitations outlined in the authorization, the state-licensed pharmacist should refer patients for clinical evaluation to prescribe drugs if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function
- Sufficient information is not available to assess for a potential drug interaction
- Modification of other medications is needed due to a potential drug interaction
- Paxlovid is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which it would not be feasible to monitor

Paxlovid is comprised of nirmatrelvir, a SARS-CoV-2 protease inhibitor, co-packaged with ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. Paxlovid is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions. Co-administration of Paxlovid can alter the plasma concentrations of other drugs and other drugs may alter the plasma concentrations of Paxlovid. Consider the potential for drug interactions prior to and during Paxlovid therapy and review concomitant medications during Paxlovid therapy. Paxlovid is not recommended in patients with severe renal impairment (eGFR<30 mL/min) until more data is available. No pharmacokinetic or safety data are available regarding the use of nirmatrelvir or ritonavir in subjects with severe hepatic impairment; therefore, Paxlovid is not recommended for use in patients with severe hepatic impairment.

Paxlovid is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Paxlovid unless the authorization is terminated or revoked sooner.

Pharmacists' ability to prescribe this medication to aid in the treatment of patients is a significant step in the pharmacists' role in overall patient care. The ability to prescribe Paxlovid without a collaborative practice agreement will allow for more accessibility for patients. However, pharmacists should be cautious when prescribing, taking into consideration a full patient medical history to ensure that the benefit of Paxlovid outweighs the potential risks.

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