Paxlovid Drug Interaction Screening Checklist Updated

The FDA has updated a checklist designed to help evaluate potential drug interactions and other patient factors before prescribing Paxlovid (copackaged nirmatrelvir and ritonavir tablets) for COVID-19. It incorporates additional guidance on drugs that should not be taken with Paxlovid or may require dose or other treatment adjustments.

In addition, the checklist’s Medical History section outlines Paxlovid prescribing requirements in line with the latest FDA Emergency Use Authorization (EUA) letter. Eligible patients must test positive for SARS-CoV-2 and be 18 years or older or 12 years or older and weigh at least 40 kg, or 88.2 lb. They must have mild to moderate COVID-19 symptoms and be at risk for progression to severe disease. When prescribing, patients must be within 5 days of symptom onset and must not require hospitalization for severe or critical COVID-19. Kidney and liver function should be assessed.

The checklist references more detailed treatment and prescribing information, including the National Institutes of Health COVID-19 treatment guidelines and the FDA Paxlovid factsheet. Intended as a clinical decision-making aid for prescribers including pharmacists, the checklist’s use is not required to prescribe Paxlovid under the EUA, the agency wrote.

Online Visual Acuity Test Cleared

An online visual acuity test has gained FDA clearance.

The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application that consumers can access using a touchscreen mobile device and internet-connected computer, according to a company statement. It is intended for use by adults aged 22 to 40 years who are capable of performing a self-test at home to help evaluate visual acuity, the FDA said.

Completed vision test results are forwarded to eye care professionals for evaluation and follow-up, which may include corrective lens prescription renewal online or referral for an in-person eye examination. This device does not provide screening or diagnosis of eye health or other disease and does not replace an eye health examination with a licensed clinician, the FDA said.

New Philips BiPAP Recall

Philips Respironics recalled certain bilevel positive airway pressure (BiPAP) machines that may contain contaminated plastic, the FDA warned. That plastic may release certain chemicals called volatile organic compounds (VOCs) or cause machine failure.

The recall involves the 386 A-Series BiPAP A30 (ventilator), A-Series BiPAP A40 (ventilator), A-Series BiPAP V30 (auto ventilator), and OmniLab Advanced + machines. The affected machines’ serial numbers can be downloaded on the FDA’s warning page.

Although the new recall includes some machines recalled in June 2021 due to plastic foam issues, the 2 recalls are not related, the agency said.

Inhaling VOCs could cause headaches; dizziness; and irritation of the eyes, nose, respiratory tract, and skin; hypersensitivity reactions including allergic or other immune system reactions; nausea or vomiting; or other toxic and cancer-causing effects. BiPAP machine failure could cause death or serious injury. Although the FDA has no reports of deaths or serious injuries associated with the newly recalled devices, any health issue or problem with the machines should be reported.

- Howard D. Larkin

Note: Source references are available through embedded hyperlinks in the article text online.