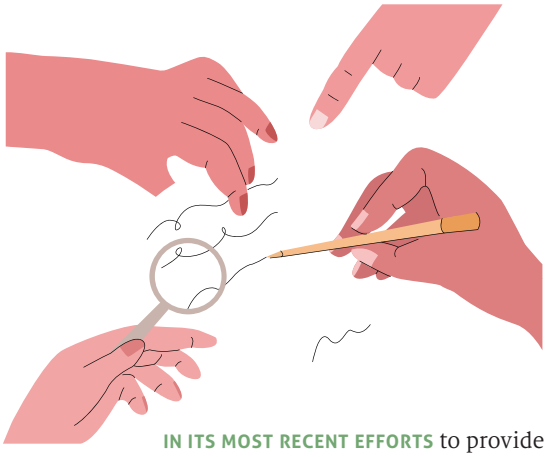

Pharmacists Are Empowered Yet Again

FDA Revises Emergency Use Authorization to Grant Prescribing Authority for Pfizer's Paxlovid Antiviral Treatment for COVID-19

By NED MILENKOVICH, PHARMD, JD

IN ITS MOST RECENT EFFORTS to provide public access to COVID-19–related medications, the FDA is now allowing state-licensed pharmacists to prescribe the nirmatrelvir and ritonavir combination (Paxlovid), an antiviral treatment produced by Pfizer Inc.[1]

The medication is intended for individuals at high risk for severe disease who had a recent infection. The FDA expanded this authorization in its most recent revision to its emergency use authorization.

The FDA's move represents yet another expansion of pharmacist prescribing ability in a continuing cycle of growth and expanded services for the profession. Before this expansion, only other licensed professionals were allowed to prescribe this treatment. These included advanced-practice nurses, physician assistants, and physicians. The trend to expand pharmacist services continues, and this is another testament to the significant role pharmacists play in communities. Although COVID-19 has been an entry portal into expanded services that pharmacists delivered during the pandemic's peak, many of the services have the potential to morph into other mainstay services that patients could seek out at their local community pharmacies.

Nirmatrelvir and ritonavir is an oral antiviral drug with 30 tablets intended to be dosed orally for 5 days. As soon as a patient has been positively diagnosed, therapy should begin. Ideally, therapy should commence within 5 days of symptom onset. The FDA has authorized the medication for emergency use to treat mild to moderate cases of coronavirus in individuals at high risk for severe COVID-19. The drug is thought to be useful for patients who live in isolated or rural areas and for those who may not have immediate access to a clinic or physician. Additionally, individuals who are traveling may also benefit from immediate access to a local pharmacy should they become ill in transit.

The fact that pharmacists are so accessible is no surprise because pharmacies are located in many places. As a result, the ancient idea of a pharmacist being a primary access point has resurfaced over the past several years. Empowering pharmacists to prescribe and dispense nirmatrelvir and ritonavir is just another step in that direction.

The FDA has approved nirmatrelvir and ritonavir for individuals older than 12 years who weigh at least 88 pounds. High-risk patients who are immunocompromised or older than 65 years and have an increased risk of hospitalization or death are the targeted population for nirmatrelvir and ritonavir.

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Patients seeking nirmatrelvir and ritonavir from a pharmacist must meet specified eligibility criteria before the drug can be prescribed and dispensed. Specifically, they must be able to provide:

- a complete list of medications they are taking, including OTC medications, so the pharmacist can screen for drugs that could have potential serious interactions with nirmatrelvir and ritonavir; and
- complete electronic or printed health records that are not more than a year old. These must include the most recent reports of laboratory blood work to determine eligibility for nirmatrelvir and ritonavir and provide insight into hepatic or renal drug clearance issues. The pharmacist can also obtain this information directly from the patient's health care provider. Modifications to the dosing regimen may be required, depending on patient kidney and liver function.

To the extent that a patient is unable to provide a list of all medications and updated health records or if a dosage adjustment is needed to make nirmatrelvir and ritonavir safer to take, pharmacists have the option to refer a patient to an advanced-practice nurse, a physician assistant, or a physician.

The FDA in no way prohibits other health care practitioners from prescribing and dispensing nirmatrelvir and ritonavir The point of the revised emergency use authorization was to expand access points to include pharmacists as recognized health care professionals who can prescribe and dispense such medications.

Patients can qualify for nirmatrelvir and ritonavir if they have tested positive for COVID-19 and are at high risk for developing severe disease. Although pharmacists have been added to the list of health care professionals able to prescribe nirmatrelvir and ritonavir the FDA is not deterring patients from seeing their regular health care providers. The inclusion of pharmacists in the care of patients for COVID-19 provides an additional access point but should not be construed as the only access point. Of course, when advanced-practice nurses, physician assistants, and primary care physicians are not available or are difficult to access, pharmacists should be the contact point for patients. Regardless, the pharmacist authorization can fill a major gap and access point. It also presents pharmacists with another opportunity for patient care.

At a minimum, the expansion of access to pharmacists is a step toward expanded treatment access by patients who may otherwise not have a primary care physician or other health care provider who can assist them. ■

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