December 27th, 2021

COM-2021-058

Dear provider of healthcare-related services,

We all have important roles in the front lines of the 2019 coronavirus disease (COVID-19) pandemic that we are facing. As the COVID-19 pandemic continues to evolve, PharmPix is making every possible effort to continue to provide our essential services to assure the use of appropriate medications by the appropriate patients at the right moment, while also caring for the safety of our employees, their families, and the community in general.

The U.S. Food and Drug Administration issued back-to-back emergency use authorizations (EUAs) for two oral direct-acting antivirals (DAAs): Pfizer's Paxlovid™ and Merck's molnupiravir.

Paxlovid™

Pfizer's Paxlovid™ includes nirmatrelvir, a SARS-CoV-2 main protease inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A4 inhibitor. It is indicated for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

The medication should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset. The recommended dosage is 300mg of nirmatrelvir (two tablets of 150mg) with 100mg ritonavir (one 100mg tablet), with all three tablets taken together twice daily for five days. It is not recommended in patients with severe renal impairment or severe hepatic impairment.

The authorization of Paxlovid™ was based on the EPIC-HR study (NCT04960202), which reduced the risk of hospitalization or death by 90% (when taken within 3 days of symptom onset) and 88% (when taken within 5 days of symptom onset) compared to placebo.

Molnupiravir

Merck's molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

The medication should be initiated as soon as possible after the diagnosis has been made, and within 5 days of symptom onset. The recommended dosage is 800mg (four 200mg capsules) taken orally every 12 hours for 5 days, with or without food.

The authorization of molnupiravir was based on the MOVe-OUT study (NCT04575597), which reduced the risk of hospitalization or death by 30% (when taken within 5 days of symptom onset) compared to placebo.

Please refer to the following resources for more information:

1. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid™
2. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Molnupiravir
3. FDA News Release for Paxlovid™
4. FDA News Release for Molnupiravir

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most updated information.

PharmPix is committed to the health and wellness of our members, and to support you as the COVID-19 pandemic continues to evolve. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 220.

Kind regards,

Clinical Department