Ohio | Department of Health

Mike DeWine, Governor
Jon Husted, Lt.Governor

Bruce Vanderhoff, MD, MBA, Director

MEMORANDUM

DATE: Dec. 28, 2021

TO: Ohio Healthcare Providers

FROM: Bruce Vanderhoff, MD, MBA, Director of the Ohio Department of Health

SUBJECT: Emergency Use Authorization for Two COVID-19 Oral Therapeutics

Two oral therapeutics, Pfizer's Paxlovid and Merck's molnupiravir, were recently granted emergency use authorization (EUA) by the U.S. Food and Drug Administration (FDA) for the treatment of COVID-19. While these oral treatments offer the promise of yet more tools in our COVID-19 toolbox, they are for treating sick people unlike the vaccines, which are designed to protect you from serious illness, hospitalization, or death.

A limited supply of these new oral therapeutics is being allocated to Ohio by the federal government. Due to the limited supply, the state is utilizing a selection of the existing monoclonal providers to distribute the medication on day one. As supply becomes more readily available, the state will expand to additional providers.

Pfizer's Paxlovid

Pfizer's Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) has been granted EUA by the FDA for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients ages 12 and older weighing at least 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. Paxlovid is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and **within five days of symptom onset**.

- Paxlovid is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in those requiring hospitalization due to severe or critical COVID-19. It is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended.
- Paxlovid consists of nirmatrelvir, which inhibits a SARS-CoV-2 protein to stop the virus from replicating, and ritonavir, which slows down nirmatrelvir's breakdown to help it remain in the body for a longer period at higher concentrations. Paxlovid is administered as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) taken together orally twice daily for five days, for a total of 30 tablets. Paxlovid is not authorized for use for longer than five consecutive days.

- More information about Paxlovid, including dosing instruction, potential side effects, drug interactions, warnings/precautions, contraindications, specific populations, and information about who is able to prescribe Paxlovid, is available in the FDA's Fact Sheet for Healthcare Providers.

Merck's molnupiravir

Merck's molnupiravir (MD-4482) has been granted EUA by the FDA for the treatment of mild-to-moderate COVID-19 in adults ages 18 and older with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 including hospitalization and death, and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate. Molnupiravir is available by prescription only and **should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset**.

- Molnupiravir is a medication that works by introducing errors into the SARS-CoV-2 virus' genetic code, which prevents the virus from further replicating. Molnupiravir is administered as four 200 milligram capsules taken orally every 12 hours for five days, for a total of 40 capsules. Molnupiravir is not authorized for use for longer than five consecutive days.
- Molnupiravir is not authorized for use in patients younger than 18 years of age because molnupiravir may affect bone and cartilage growth. It is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to COVID-19 because benefit of treatment has not been observed in people when treatment started after hospitalization due to COVID-19. It is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended.

More information about molnupiravir, including dosing instructions, potential side effects, drug interactions, warnings/precautions, contraindications, specific populations, and information about who is able to prescribe Molnupiravir, is available in the FDA's Fact Sheet for Healthcare Providers.

How to Request Oral Therapeutics

The U.S. Department of Health and Human Services (HHS) oversees this process, and makes allocations to states looking at factors including case rates and hospitalizations.

At this time, Ohio's allocations are being made by the Ohio Department of Health (ODH) in cooperation with state partners including the Ohio Department of Aging, healthcare associations, and clinical zone leadership to ensure equitable distribution. The goal of Ohio's state-coordinated distribution system is to maintain equitable distribution geographically and across different types of facilities (hospitals and healthcare systems, long-term care facilities/pharmacies, and federally qualified health centers), factoring in current supply and

utilization. With the initial supply of oral therapeutics being extremely limited, distribution will be focused on the smallest number of providers who have experience with the federal allocation system through the monoclonal antibody system, and who provide the greatest level of access statewide.

The supplies are maintained and distributed by a wholesaler (AmerisourceBergen) contracted through HHS, and are never possessed by the state. ODH's role is to facilitate allocations and ensure fair and equitable distribution.

ODH will share updated guidance on COVID-19 treatment options as new products become available. If you have any questions, you may contact ODH at **hpp@odh.ohio.gov** for additional information.

Vaccine providers with questions may call the ODH Provider Call Center at 1-844-9ODHVAX (1-844-963-4829) between 8 a.m. and 7 p.m. Mondays through Fridays or email COVIDVACCINE@odh.ohio.gov. Please note that effective Jan. 1, 2022, the Provider Call Center hours will change to 8 a.m. to 5:30 p.m. Monday through Friday.

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