Updated February 22, 2022
DOH 821-160

Interim DOH Guidance for Use of Molnupiravir

Updates (February 22, 2022):

- Removed the recommendations for use in the case of logistical and/or supply constraints
- Expanded eligibility criteria for consideration
- Added therapeutic information and locator tool

About Molnupiravir

On December 23, 2021, the FDA provided an EUA for Molnupiravir, which is limited for use for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, **and** who are at high-risk for progression 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.

Molnupiravir consists of a single medication for oral use. It is authorized for people age 18 or older. The course of treatment is 800 mg (four 200 mg capsules) taken orally every 12 hours for five days, with or without food. It is only indicated for five days and the prescription includes 40 tablets. Molnupiravir is currently available at Safeway, Save-on, Haggen's, CVS, Walgreens, Rite-Aid pharmacies, as well as numerous independent pharmacies throughout Washington. Locations can be found using the following locator: COVID-19 Therapeutics Locator.

Recommendations

The following recommendations should be used to ensure equitable administration for those individuals who might receive the greatest benefit from SARS-CoV-2 treatment. These recommendations are not prescriptive, but rather should be used in the context of clinical decision-making and other community factors to determine the best treatment option for the specific patient, consistent with current NIH guidelines. The following underlying conditions increase the risk for progression to severe disease:

- ≥ 65 years of age
- Cancer
- Cardiovascular disease or hypertension
- Chronic kidney disease
- Chronic lung diseases
- Chronic liver diseases
- Complex genetic or metabolic syndromes
- Diabetes
- Downs syndrome
- HIV infection
- Immunosuppression
- Limited access to care or members of communities disproportionately impacted by COVID-19

- Moderately-to-severely immunosuppressed
- Medical-related technological dependence
- Neurodevelopmental disorders
- Obesity (BMI ≥25 kg/m2)
- Sickle cell disease or thalassemia
- Severe congenital anomalies
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease
- Tobacco usage, current or former
- Substance use disorders
- Tuberculosis

Authorization of molnupiravir under its EUA is not limited to the medical conditions or factors listed above. Other medical conditions or factors may also place individual patients at high risk for progression to severe COVID-19; see Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19 and People with Certain Medical Conditions.

Per the EUA, molnupiravir is authorized for patients hospitalized for reasons other than COVID-19 with mild-to-moderate symptoms of COVID-19 (confirmed with positive results of a direct SARS-CoV-2 viral test) if the patient is also at high risk for progression to severe COVID-19, including hospitalization or death and the terms and conditions of the authorization are met, as detailed in the Fact Sheet for Health Care Providers.

Limitations on Authorized Use

Molnupiravir is not authorized for use in patients who are less than 18 years of age.

Molnupiravir is not authorized for initiation of treatment in patients requiring hospitalization due to COVID-19. Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization
due to COVID-19.

Molnupiravir is not authorized for use for longer than 5 consecutive days.

Molnupiravir is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.

Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., anti-infectives).

Warning

Pregnancy - Molnupiravir may cause fetal harm when administered to pregnant individuals. Therefore, **molnupiravir is not recommended for use during pregnancy**. Prior to initiating treatment with molnupiravir, health care providers should assess whether an individual of childbearing potential is pregnant or not, if clinically indicated. Molnupiravir is authorized to be prescribed to a pregnant individual **only** after the health care provider has determined that the benefits would outweigh the risks for that individual patient and the known and potential benefits and potential risks of using molnupiravir during pregnancy are communicated to the pregnant individual.

Lactation - Breastfeeding is **not recommended during treatment with molnupiravir and for four days after the final dose.** A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.

Females of Reproductive Potential - Females of childbearing potential are advised to use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for four days after the last dose of molnupiravir.

Males of Reproductive Potential - While the risk is regarded as low, studies to fully assess the potential for molnupiravir to affect offspring of treated males have not been completed. Sexually active individuals with partners of childbearing potential are advised to use a reliable method of contraception correctly and consistently during treatment and for at least three months after the last dose of molnupiravir. The risk beyond three months after the last dose of molnupiravir is unknown. Studies to understand the risk beyond three months are ongoing.

References

- IDSA guidance: IDSA Guidelines on the Treatment and Management of Patients with COVID-19 (idsociety.org)
- Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers
- CDC Altered Immunocompetence
- CDC Yellow Book – Chapter 5 Immunocompromised Travelers
- Fact sheet for Patients and Caregivers
- Fact sheet for Providers
- FDA FAQ for Molnupiravir
- People with Certain Medical Conditions

More COVID-19 Information and Resources

- Stay up-to-date on the current COVID-19 situation in Washington, Governor Inslee's proclamations, symptoms, how it spreads, and how and when people should get tested. See our Frequently Asked Questions for more information.
- The risk of COVID-19 is not connected to race, ethnicity or nationality. Stigma will not help to fight the illness. Share accurate information with others to keep rumors and misinformation from spreading.
- WA State Department of Health 2019 Novel Coronavirus Outbreak (COVID-19)
- WA State Coronavirus Response (COVID-19)
- Find Your Local Health Department or District
- CDC Coronavirus (COVID-19)
- Stigma Reduction Resources

Have more questions about COVID-19? Call our hotline: **1-800-525-0127.** For interpretative services, **press #** when they answer and **say your language**. (Open from 6 a.m. to 10 p.m.) For questions about your own health, COVID-19 testing, or testing results, please contact your health care provider.
To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.