

# Molnupiravir for COVID-19

## Emergency Use Authorization (EUA) Requirements: Mar 2022

VA Pharmacy Benefits Management Services

Molnupiravir has been authorized by the FDA Emergency Use Authorization ([EUA](#)) to treat adults who meet specific criteria for COVID 19. Although it is currently available, it is NOT an FDA-approved drug for the treatment of COVID-19. Use of this product under the EUA for treatment of COVID-19 must be consistent with and may not exceed terms of the Authorization.

**Molnupiravir may only be used for the management of COVID-19 when the following criteria and requirements are met:**

The answer to ALL of the following questions should be YES for the patient to qualify for treatment with MOLNUPIRAVIR

Q1. The patient has laboratory confirmed mild to moderate COVID-19 and is within 5 days of symptom onset*	YES NO
Q2. The patient has at least one high-risk criteria for progression to severe disease, as defined by the CDC ( <a href="#">People with Certain Medical Conditions   CDC</a> )	YES NO
Q3. Alternative treatments authorized for mild-moderate COVID-19 in high risk patients are not accessible or clinically appropriate (as per FDA EUA documents)**	YES NO
Q4. The prescribing healthcare provider has reviewed the information contained within the “Fact Sheet for Patients and Caregivers” with the patient or caregiver prior to the patient receiving this agent, <u>including all information required as per the FDA EUA.</u> ** The provider has provided the patient/caregiver with an electronic or hard copy of the fact sheet.	YES NO
Q5. If the patient is a female of childbearing potential, or is a male of reproductive potential who is sexually active with a female of childbearing potential, they agree to use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment <u>and for 4 days (females) or 3 months (males) after the last dose of molnupiravir.</u> For females of childbearing potential pregnancy status has been determined to be negative (unless the patient is surgically sterilized, has an intrauterine device or contraceptive implant or is unable to get pregnant). If patient is pregnant select NO and review question 6 closely.***	YES NO
Q6. If the patient is pregnant, and MOV is to be used during pregnancy, ALL of the following has been done: the provider has communicated the known and potential risks of MOV during pregnancy and documented the same, the provider has made the pregnant patient aware of the Merck pregnancy surveillance program, and if the patient agrees to participate and allows the provider to disclose patient specific information, the provider has provided the patient’s name to Merck. (Answer YES if the patient is not pregnant)****	YES NO

\* Given a potentially limited supply and to ensure appropriate use consistent with the EUA requirements, COVID-19 testing for the purposes of prescribing EUA products should ideally be done through the VA facilities. However, if logistical issues precluding testing through VHA, the following guidance should be followed. Testing should be performed in accordance with the FDA Emergency Use Authorization instructions and guidance to Veterans regarding at-home testing. A decreasing order of preference for confidence in self-testing is that: a. The test is performed under direct observation (proctored), e.g. during a VVC telehealth visit, b. The test is not performed under direct observation (un-proctored), but an image of the test is made available to the provider (e.g. by secure messaging or during a VVC telehealth visit. c. The test is un-proctored and an image is not available, but the result is verbally reported to the provider

\*\*Currently, several drugs are authorized under FDA EUA for the treatment of mild-moderate COVID-19, including Paxlovid, Sotrovimab and Bebtelovimab. Sotrovimab is not authorized for treatment of BA.2 variant. Remdesivir is recommended by the [NIH](#) as off-label use but is not considered.

\*\*\*PBM will review and approve medication if appropriate. Do not dispense without approval for pregnant patients.

\*\*\*\*The prescribing healthcare providers must inform the patient/caregiver that: Molnupiravir is an unapproved drug that is authorized for use under EUA, that there are no adequate, approved, available products for treatment of COVID-19 in adults who have mild-to-moderate COVID-19 and are at high risk for progressing to severe COVID-19, including hospitalization or death. The provider must inform patients that other therapeutics are currently authorized for the same use as molnupiravir, as found on the [FDA EUA website](#), that there are benefits and risks of taking molnupiravir, that Merck Sharp & Dohme has established a pregnancy surveillance program, and non-pregnant adults of childbearing potential agree to use adequate, consistent contraception as outlined above (Q5)

### **Suggested Dosing and Administration per the EUA**

- Recommended dose in adults is 800mg orally q12h for 5 days (with or without food) with no dose adjustments recommended for renal or hepatic impairment or in geriatric patients.

### **Monitoring and Reporting of Adverse Events**

- Providers must report all medication errors and serious adverse drug events possibly related to MOV through the VA ADERS program
- Given the potential for embryo-fetal toxicity based on animal studies, providers are required to take additional actions if they do prescribe MOV to a pregnant person.

### **VHA Specific Request Process:**

- Facilities interested in obtaining MOV
  - Must visit the [PBM SharePoint](#) site to register their site by providing mailing address and phone number for pharmacy and pharmacy point of contact
  - Opt-in to receiving shipments of MOV
- ASD will ship using appropriate delivery to sites
  - Sites are required to 'receive' shipments once they arrive to acknowledge receipt and appropriate storage
- Once supply is on hand an in-line patient request form will be entered to ensure all required EUA tracking information is captured **PRIOR TO INITIATION OF TREATMENT**, including
  - Patient name, last 4 of SSN and date of birth, and date of positive COVID-19 test
  - Confirmation that the patient has laboratory confirmed mild to moderate COVID-19 diagnosis (MOLNUPIRAVIR is not authorized in patients who are hospitalized due to COVID)
  - Confirmation that administration will be within 5 days of symptom onset
  - Confirmation that the patient is at high risk for progression to severe disease per the updated CDC criteria
  - Confirmation that the other EUA treatments for mild-moderate COVID-19 are inaccessible or not clinically appropriate
  - Confirmation that the patient has been provided the "fact sheet for patients and caregivers" and that this is documented
  - Confirmation that if the patient is a female of childbearing potential, pregnancy status has been determined (unless the patient is surgically sterilized, has an intrauterine device or contraceptive implant or is unable to get pregnant). If the patient is not pregnant or is a male who is sexually active with a female of childbearing potential, the prescriber has explained that a reliable method of contraceptive should be used consistently during therapy and for up to 4 days after treatment (females) or 3 months after treatment (male partners of females of childbearing potential)
  - IF the provider decides to prescribe MOV during pregnancy, they must inform the patient that MOV is an unapproved drug, that there are no adequate approved products for treatment of mild-moderate COVID-19 in adults, that there ARE other products under EUA for the same use as MOV, that there are potential benefits and risks of use during pregnancy (as outlined in the patient fact sheet), that Merck has established a pregnancy surveillance program - **Consider use of the [MOLNUPIRAVIR prescriber checklist](#) to ensure all required elements are communicated and documented**
  - Once all boxes are checked appropriately, an automatic approval notice will be generated with a link to a follow up form, on which the site will be asked to track the following
    - Date the drug was dispensed to the patient and the order number
    - Number of doses and dose dispensed
    - Lot numbers dispensed to the patient
    - If any adverse events occurred and if they were properly documented via local policy AND also VA ADERS
    - Certification that all information is accurate and complete. Records marked as complete will be subtracted from available stock and used for future allocation

Additional information: [FDA EUA Fact Sheet for Health Care Providers](#)