

# VIRGINIA MOLNUPIRAVIR (LAGEVRIO) EMERGENCY USE CHECKLIST



Last Updated: 7.1.2022

*This checklist is intended as an aid to support clinical decision making for prescribers. This form may be completed by the prescribing provider or designee to assist in determining patient eligibility for molnupiravir (LAGEVRIO). This checklist is not a requirement, however, it will help providers understand the currently available evidence, resources, information, emergency use authorization (EUA) requirements and expert opinions. This checklist is subject to change.*

Prescribing Provider Name: \_\_\_\_\_ Date and time of prescription: \_\_\_\_\_

Patient name: \_\_\_\_\_ Patient Date of Birth: \_\_\_\_\_

## MEDICAL HISTORY

- Positive** SARS-CoV-2 test (Confirmation of a positive home rapid SARS-CoV-2 test result with additional direct SARS-CoV-2 viral testing is not required.)
- Age  $\geq$  **18** years of age
- Has one or more **risk** factors for progression to severe COVID-19 (Healthcare providers should consider the benefit-risk for an individual patient.)
- Symptoms consistent with mild to moderate COVID-19
  - Symptoms **may** include: Cough, Shortness of breath or difficulty breathing, Fever, Chills, Muscle pain, Sore throat, GI symptoms, Diarrhea
- Symptom onset within **5 days** (Prescriber is encouraged to include a note to the pharmacist in the prescription stating: Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.)
- Not** requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- Alternative COVID-19 treatment options authorized by the **FDA** are not accessible or clinically appropriate
- The prescribing healthcare provider **must** assess whether a female of childbearing potential is pregnant or not, if clinically indicated

## EXCLUSION CRITERIA

Any below are contrary to authorized use.

- Patient is less than **18 years** of age
- Known hypersensitivity to any ingredient of **molnupiravir**
- Initiation of treatment in a patient hospitalized due to COVID-19
- For use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19
- For use after patient has had symptoms for **5 days**

## MOLNUPIRAVIR DOSING AND COUNSELING

- **800 mg** (four 200 mg capsules) taken orally every **12 hours** for **5 days**, with or without food
- Completion of the **full** 5-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2 (Note: Not authorized for use for longer than 5 consecutive days)
- The prescribing healthcare provider and/or the provider's designee must report all medication errors and serious adverse events potentially related to **molnupiravir** within **7 calendar days** from the healthcare provider's awareness of the event
- **No** adjustment needed for renal or hepatic impairment or in geriatric patients
- Advise patients on need for contraception use as appropriate
  - Females of childbearing potential treated: should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of **molnupiravir**
  - Males of reproductive potential treated: if sexually active with females of childbearing potential, should use a reliable method of contraception correctly and consistently during treatment and for at least **3 months** after the last dose

## INDIVIDUALS OF CHILDBEARING POTENTIAL

- Assess** whether pregnant or not
  - Report of LMP in an individual who has regular menstrual cycles, uses a reliable method of contraception correctly and consistently or has had a negative pregnancy test
- Negative pregnancy test (recommended but **not** required if other criteria are not met)
- If pregnant:**
  - Counsel the patient regarding the known and potential benefits and potential risks of **molnupiravir** use during pregnancy
  - Document that the patient is aware of the known and potential benefits and potential risks of **molnupiravir** use during pregnancy

It **MUST** be documented in the patient's medical record prior to prescribing of **molnupiravir** that **informed consent** process took place, in which the risks, benefits, unknowns of the proposed treatment, and reasonable treatment alternatives were discussed with patient/surrogate and their acceptance or refusal documented and the **patient/surrogate has been provided the following:**

- The **Fact Sheet** for Patients and Parents/Caregivers
- Informed of alternatives to receiving **molnupiravir**
- Informed that **molnupiravir** is an unapproved drug that is authorized for use under EUA

If a serious and unexpected adverse event occurs and appears to be associated with the use of **molnupiravir**, the prescribing health care provider and/or the provider's designee shall complete and submit a MedWatch form within 7 calendar days from the onset of the event to the FDA using one of the following methods:

- Complete and submit the **report** online, or
- Use a postage-paid **Form FDA 3500** and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (**1-800-FDA-0178**), or
- Call **1-800-FDA-1088** to request a reporting form