

Prescriber Certification of Requirements for Use of Molnupiravir

Date: _____ Time: _____

I am an individual authorized under Washington State Law to prescribe medications. I have reviewed the Emergency Use Authorization Fact Sheet for Healthcare Providers. I certify that all of the following requirements for the use of molnupiravir have been met for my patient

_____.

- 1) This patient is in need of treatment of mild-to-moderate COVID-19 and is an adult with a positive result of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who is 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;
- 2) I have reviewed the information contained within the “Fact Sheet for Patients and Caregivers” with this patient or the patient’s caregiver prior to the patient receiving molnupiravir. The patient or the caregiver has been provided with an electronic or hard copy of the “Fact Sheet for Patients and Caregivers” prior to the patient receiving molnupiravir;
- 3) I have informed the patient/caregiver that:
 - a. Molnupiravir is an unapproved drug that is authorized for use under an Emergency Use Authorization.
 - b. There are no adequate, approved, available products for the 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.
 - c. Other therapeutics are currently authorized for the same use as molnupiravir. For additional information on all products authorized for treatment or prevention of COVID-19, please see <https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization>.
 - d. There are benefits and risks of taking molnupiravir as outlined in the “Fact Sheet for Patients and Caregivers.”
 - e. Merck Sharp & Dohme has established a pregnancy surveillance program.
 - f. Females of childbearing potential 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.
 - g. Males of reproductive potential who are 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.
- 4) I have assessed if this patient is a female of childbearing potential is pregnant or not, if clinically indicated.
- 5) If molnupiravir is used during pregnancy, I have communicated to the patient and discussed with the patient the known and potential benefits and the potential risks of molnupiravir use during pregnancy, as outlined in the “Fact Sheet for Patients and Caregivers” and I have documented this communication and discussion in a separate progress note in the resident’s clinical record.

- 6) I have documented in a separate progress note in the patient's clinical record that a pregnant individual was made aware of Merck Sharp & Dohme's pregnancy surveillance program at 1-877-888-4231 or pregnancyreporting.msd.com. If the pregnant individual agrees to participate in the pregnancy surveillance program and allows the prescribing healthcare provider to disclose patient specific information to Merck Sharp & Dohme, the prescribing healthcare provider must provide the patient's name and contact information to Merck Sharp & Dohme, and I have entered a separate progress note in the patient's clinical record that this information has been provided to Merck Sharp & Dohme.
- 7) I and/or my designee agree to the reporting of all medication errors and serious adverse events potentially related to molnupiravir within 7 calendar days from my awareness of the event.

(Signature of the Prescriber)