Prescriber Checklist Tool

Molnupiravir

Updated 1/27/2022

Patient eligibility

The FDA has issued an emergency use authorization (EUA) for Molnupiravir for the **treatment** of COVID-19 in the following individuals:

- ❑ For whom an alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate, and
- ❑ Testing positive for SARS-CoV-2, and
- ❑ Aged ≥18 years, and
- ❑ Having symptoms consistent with mild to moderate COVID-19, and
- ❑ Having symptom onset within 5 days*, and
- ❑ At high risk for progression to severe COVID-19**, and
- ❑ Not hospitalized due to COVID-19.

Requirements

Requirements prior to any eligible patient receiving Molnupiravir under EUA

- ❑ Provide an electronic or hard copy of Fact Sheet for Patients and Caregivers to the patient/caregiver, and document this action.
- ❑ Review the Fact Sheet for Patients and Caregivers with the patient or their caregiver and counsel the patient on the potential benefits and risks of Molnupiravir.
- ❑ Advise patients being treated with Molnupiravir on need for contraception use, as appropriate.
  - Females of childbearing potential should use a reliable method of contraception correctly and consistently for the duration of treatment and for 4 days after the last dose.
  - Males of reproductive potential who are sexually active with females of reproductive potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.

Additional requirements for female patients of reproductive potential, prior to receiving Molnupiravir

- ❑ Assess whether an individual is pregnant or not, if clinically necessary:
  - A pregnancy test is recommended (but not required) for individuals who have irregular menstrual cycles, are unsure of the first day of last menstrual period, or who are not using effective contraception correctly and consistently.
- ❑ If pregnant:
  - Counsel the patient regarding the known and potential benefits, and potential risks of Molnupiravir use during pregnancy, and document this action.
  - Make the individual aware of the pregnancy surveillance program and provide the patient's information to Merck (if the patient agrees to participate in this program) at 1-877-888-4231 or pregnancyreporting.msd.com.
- ❑ If not pregnant:
  - Make the individual aware of the pregnancy and surveillance program and encourage them to participate should they become pregnant.

Important notice

The prescribing healthcare provider and/or 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 to FDA MedWatch.

* Prescriber is encouraged to include a note in the prescription alerting the dispensing pharmacist of the "prescription fill by date," which should be within 5 days from symptom onset to comply with the patient eligibility criteria under the EUA.

**Per the EUA, high-risk patients had one or more of the following: over 60 years of age, diabetes, obesity (BMI ≥30), chronic kidney disease, serious heart conditions, chronic obstructive pulmonary disease, or active cancer.