Clinical Provider Briefing Sheet

Molnupiravir - Oral Antiviral from Merck

On December 23, 2021, the US Food and Drug Administration (FDA) granted Emergency Use Authorization to Merck for the oral antiviral drug molnupiravir. More information about molnupiravir is available from FDA:

Emergency Use Authorization
Provider Fact Sheet
Patient and Caregiver Fact Sheet
Frequently Asked Questions

In addition, the US Centers for Disease Control and Prevention (CDC) issued a Health Alert Network Advisory on using therapeutics to prevent and treat COVID-19 and the National Institutes of Health has provided updated COVID-19 Treatment Guidelines. Information is also available on the DPH COVID-19 therapeutics website.

Logistics: Distribution via USG/States

The U.S. government has purchased approximately 3 million molnupiravir treatment courses, which are being distributed by allocation through state and territorial health departments. In Connecticut, initial distributions will be available through hospitals, long-term care pharmacies, and some federally qualified health centers. As supplies increase, it is anticipated that the product will become more widely available, including through retail pharmacies. For more information about ordering molnupiravir or where it is available in Connecticut, please contact COVIDmeds.DPH@ct.gov

All sites that order antiviral drugs will have to attest to adhering to the following minimum program requirements:

- o Dispense or administer COVID-19 therapeutics consistent with FDA authorization and in accordance with guidance from the U.S. Department of Health and Human Services (HHS).
- o Report data on how many courses of COVID-19 therapeutics have been dispensed or administered, and on-hand inventory information. All required data will be reported through HHS designated systems in defined reporting capacity.
- o Not charge patients for drug costs. HHS is making COVID-19 therapeutics available at no cost to authorized providers.
- o Dispense COVID-19 therapeutics regardless of the therapeutic recipient's coverage status or ability to pay for COVID-9 therapeutics dispensing fees. Provider may seek appropriate reimbursement from a program or plan that covers COVID-19 therapeutics dispensing fees for the therapeutics recipient. Costs should not be a barrier to patient access for these medications.

Sites receiving and dispensing USG-purchased antivirals must report daily on the number of courses dispensed and inventory on hand through the HHS Health Partner Order Portal (HPoP). Reporting instructions are available in HPoP help section in the Provider User Guide.

DPH will assist with enrolling providers in HPoP and will offer office hours weekly on Tuesdays at 1pm. For more information or questions about logistics or reporting, please contact COVIDmeds.DPH@ct.gov.

Authority to Dispense

Prescribing Practitioners may dispense Molnupiravir in accordance with Chapter 370, Sections 20-14c through 20-14g which cannot be delegated unless dispensed from an emergency department, in which case it may be delegated only to a registered nurse.

Prescribers who will dispense to patients should notify the Commissioner of Consumer Protection that they are engaged in the dispensing of drugs. This notification may be provided by email to the following address: DCP.DrugControl@ct.gov.

At a minimum, prescribing practitioners are responsible for the following:

A record of the dispensation shall be made in the patient's chart.

The prescribing practitioner shall label the container with the following information:

(1) The full name of the patient;

(2) the prescribing practitioner's full name and address;

(3) the date of dispensing;

(4) instructions for use; and

(5) any cautionary statements as may be required by law.

Additional Resources for Clinicians

- Infectious Disease Society of America (IDSA) treatment guidelines
- ASPR Side-by-Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19
- MK-4482 Advisory Committee Background Package.docx (fda.gov)