Molnupiravir has been FDA-authorized for emergency use to treat mild-to-moderate COVID-19 among nonhospitalized, nonpregnant adults since December 2021.

### CLINICAL INFORMATION

**Eligibility:** The molnupiravir EUA covers adults 18 years of age and older who are at high risk for progressing 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. If it is decided to give molnupiravir, treatment should begin as soon as possible after diagnosis and within 5 days of symptom onset.

**Dosing:** A course of molnupiravir consists of 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days.

**Clinical Decision-Making:** In ambulatory adult patients with mild-to-moderate COVID-19 at high risk for progression to severe disease who have no other treatment options, IDSA guidelines suggest molnupiravir be initiated within 5 days of symptom onset (conditional recommendation, low certainty of evidence). NIH guidelines also suggest molnupiravir only when other antiviral options cannot be used (class CIII recommendation).

SAFETY

Pregnancy: FDA’s Fact Sheet for Health Care Providers states: “Based on findings from animal reproduction studies, molnupiravir may cause fetal harm when administered to pregnant individuals ... therefore, molnupiravir is not recommended for use during pregnancy.”

NIH’s COVID-19 Treatment Guidelines Panel states: “When other therapies are not available, pregnant people with COVID-19 who are at high risk of progressing to severe disease, particularly those who are beyond the time of embryogenesis (i.e., >10 weeks’ gestation), may reasonably choose molnupiravir therapy after being fully informed of the risks.

FDA and NIH both recommend that prescribing clinicians should document that a discussion with the patient of the risks and benefits occurred and that the patient chose this therapy after the discussion occurred.

Interactions With Other Therapeutics: No clinical drug-drug interaction studies of molnupiravir have been conducted, but no drug-drug interactions are expected based on available information.

SUPPLY & ACCESS

Distribution: Molnupiravir is currently available in limited quantities in the U.S. and is being allocated by the federal government to health departments in states, territories and jurisdictions as well as select community health centers.

For allocation details, refer to HHS’s distribution summaries; for information intended for health providers, see HHS’s COVID-19 Therapeutics Locator; for patient-facing information, refer to HHS’s Test-to-Treat COVID-19 Medication Locator.

CODING, BILLING & REPORTING

Coding:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosage</th>
<th>Package Size</th>
<th>NDC</th>
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<tr>
<td>Molnupiravir</td>
<td>200 mg/1</td>
<td>40 capsules in one bottle, plastic</td>
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Billing: Molnupiravir has been added to the Medicaid and Children’s Health Insurance Program formularies as a payable pharmacy benefit.

Reporting: Providers are required to report federally purchased course administration daily by 11:59 p.m. ET via HHS’s Health Partner Order Portal.

FURTHER INFORMATION

Real-Time Learning Network Molnupiravir Literature Reviews
FDA Molnupiravir EUA Fact Sheet for Health Care Providers
NIH Treatment Guidelines Panel Statement on Patient Prioritization
NIH Treatment Guidelines Panel Statement on High-Risk, Nonhospitalized Patients
University of Liverpool COVID-19 Drug Interactions