Molnupiravir FAQs

What is Molnupiravir?

Molnupiravir is an oral nucleoside analogue that introduces errors into the genetic code of SARS-CoV-2 virus, preventing the virus from further replicating. The FDA has granted an emergency use authorization (EUA) for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults who have tested positive for SARS CoV-2 who are at high risk for progression to severe COVID-19 and for whom alternative treatment options authorized by the FDA are not accessible or clinically appropriate.

Who is eligible for Molnupiravir?

Eligibility for molnupiravir will be determined based on guidance from our state or county public health departments. It will be prioritized for symptomatic patients who are at high risk for progression to severe COVID-19 in NIH tiers 3 and 4. The patients who are in NIH 1 or 2 tiers who cannot obtain other agents may receive molnupiravir.

Eligible patients:

- Must be 18 years or older
- Have a positive COVID-19 test,
- Are at high risk for severe COVID-19
- Are within 5 days of symptom onset
- Are not pregnant or breastfeeding

Molnupiravir is not authorized:

- For patients who are less than 18 years of age
- For initiation of treatment in patients hospitalized due to COVID-19
- For use for longer than 5 consecutive days
- For pre-exposure or post-exposure prophylaxis for prevention of COVID-19

*The NIH recommends using molnupiravir 800 mg PO twice daily for 5 days in those aged ≥18 years, but **only** when ritonavir-boosted nirmatrelvir (Paxlovid), sotrovimab, and remdesivir are not available or cannot be used.*

Is Molnupiravir FDA approved?

FDA has issued an EUA for the emergency use of the unapproved product molnupiravir. Emergency use authorization is NOT the same as FDA approval or licensure. Since the drug is not FDA approved, there are specific requirements for documentation.

Providers prescribing molnupiravir must review the patient fact sheet found at https://www.fda.gov/media/155055/download, discuss the medication is authorized under Emergency use authorization, and there are alternatives to molnupiravir.

Providers are encouraged to use the smartphrase called .MOLNUPIRAVIR to document the patient conversation.

- English: https://www.fda.gov/media/155055/download; or have patient text MOL to 844.520.8700 to get a text with the link
- Spanish: https://www.fda.gov/media/155115/download; or have patient text MOLS to 844.520.8700 to get a text with the link

What are the data supporting the use of Molnupiravir?

A phase 3 randomized controlled trial (MOVe-OUT) included symptomatic subjects not vaccinated against SARS-CoV-2 who had laboratory confirmed infection and symptom onset within 5 days of randomization to molnupiravir or placebo. Initial results demonstrated the primary outcome of risk of hospitalization for any cause or death through day 29 was significantly lower with molnupiravir than placebo (6.8% vs 9.7%), with an absolute risk reduction of 3% and a relative risk reduction of 30%. In terms of all-cause mortality through Day 29 there was 1 (0.1%) patient in the molnupiravir group and 9 (1.3%) patients in the placebo group. Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19. The number needed to treat to prevent one hospitalization/death is 34 patients.

What are side effects of Molnupiravir?

Molnupiravir was well-tolerated in the phase 3 clinical trial (MOVe-OUT) with the most common adverse effects reported being diarrhea, nausea, and dizziness all occurring in less than 2% of patients who received molnupiravir. However, there are limited clinical data available for molnupiravir so serious and unexpected adverse events may occur that have not been previously reported. If a patient experiences a serious side effect, the FDA must be notified by filling out an online form.

Are there drug-drug interactions or contraindications with Molnupiravir?

No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir and no clinical drug-drug interaction trials with concomitant medications have been conducted. No contraindications have been identified based on the limited available data.

What are the risks for patients of child-bearing age (males and females)?

Women of child-bearing age should remain on contraception while on therapy and at least 4 days after treatment is completed. It is not known if molnupiravir can affect sperm. A reliable method of birth control (contraception) should be used consistently and correctly during treatment with molnupiravir and for at least 3 months after the last dose. The risk beyond three months after the last dose of molnupiravir is unknown.

What are the risks for pregnant and lactating women?

The use of molnupiravir is **not recommended** in patients who are pregnant or breast-feeding. If a patient becomes pregnant while on molnupiravir, providers are advised to contact MERCK at https://pregnancyreporting.msd.com/.

Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.

What is the dose and duration of Molnupiravir?

Molnupiravir is administered as four 200 milligram capsules taken orally every 12 hours, with or without food, for five days. This is **eight capsules** per day. Molnupiravir is not authorized for use for longer than five consecutive days and should be initiated within 5 days of symptom onset. There are no dose adjustments necessary for hepatic or renal dysfunction.

How/Where will Molnupiravir be picked up or delivered?

Molnupiravir is available at SCCA pharmacy and three pharmacies within UW Medicine. Molnupiravir is not available for delivery. There are other pharmacies around the state that carry molnupiravir; See https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/ for additional locations across Washington.

SCCA Outpatient Pharmacy

206-606-6500

Harborview Medical Center: Outpatient Pharmacy
206-744-4535 Option 1
UW Medical Center Outpatient Pharmacy
206-598-4363
Northwest Pharmacy & Medical Supply
206-365-2255

Additional information:

Healthcare fact sheet: www.fda.gov/media/155054/download

Patient fact sheet: https://www.fda.gov/media/155055/download

In Spanish: https://www.fda.gov/media/155115/download

NIH guidelines for treatment:
https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/