Molnupiravir (MOV) EUA
VA Frequently Asked Questions (FAQ):
August 2022

VA Pharmacy Benefits Management Services

Background

The COVID-19 pandemic caused by a novel coronavirus has resulted in significant morbidity and mortality, and limited treatment is available for outpatients. Molnupiravir is an oral antiviral authorized by the FDA under Emergency Use Authorization (EUA) for outpatients with COVID-19 at high risk for progression. This FAQ is designed to serve as a resource for VHA physicians, pharmacists, nurses, and other healthcare personnel on the use of MOV in COVID-19, which received an EUA from the FDA on 12/23/21.

What's new in the March 2022 update? Additional information about alternative treatments is included, including what must be communicated to patients as part of the EUA requirements. In addition, post-authorization adverse event data has been added, as well as a warning for hypersensitivity reactions, including anaphylaxis.

What's new int he August 2022 update? Information about viral rebound after treatment.

Molnupiravir (MOV) EUA Indication and Requirements

- **The FDA EUA has authorized MOV ONLY if specific criteria are met**. VHA Providers should read and follow the FDA's EUA prior to prescribing MOV for a patient.
- The FDA EUA for MOV authorizes this combination for the treatment of **mild to moderate laboratory confirmed COVID-19 in individuals 18 years of age and older, with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe disease, who are within 5 days of symptom onset, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate**
  - Given a potentially limited supply and to ensure appropriate use consistent with the EUA requirements, COVID-19 testing for the purposes of prescribing EUA products should ideally be done through the VA facilities. However, if logistical issues precluding testing through VHA, the following guidance should be followed. Testing should be performed in accordance with the FDA Emergency Use Authorization instructions and guidance to Veterans regarding at-home testing. A decreasing order of preference for **confidence in self-testing is that:**
    - The test is performed under **direct observation (proctored),** e.g. during a VVC telehealth visit,
    - The test is not performed under direct observation (un-proctored), but an **image of the test is made available to the provider** (e.g. by secure messaging or during a VVC telehealth visit).
    - The test is un-proctored and an image is not available, but the result is **verbally reported to the provider** *of the positive test prior to initiating therapy.*
  - The FDA does not consider remdesivir an adequate alternative to MOV for mild-to-moderate COVID-19 due to the need for a 3 day intravenous infusion. Note: the NIH Guidelines DO list remdesivir as one of the priority treatment options, ahead of MOV, but with the FDA EUA, providers are note REQUIRED to consider remdesivir as an alternative.
- **High risk is defined in patients with one of the following criteria**:
  - Age ≥ 65 years of age
  - Cancer
  - Chronic kidney disease
  - Chronic liver disease
  - Chronic lung disease
  - Dementia or other neurological conditions
  - Disabilities (such as Down syndrome or spinal cord injuries)
  - Diabetes
  - Cardiovascular disease
  - Immunosuppressive disease or treatment
  - Body mass index (BMI) > 25 kg/m^2 in adults and physical inactivity
  - Pregnancy
  - Sickle cell disease or thalassemia
  - Stroke or cerebrovascular disease
  - Current or former smoking
  - Mental health conditions such as depression, schizophrenia and substance use disorders
  - Tuberculosis
- Other medical conditions or factor (for example, race or ethnicity) may also place individual patients at high risk for progression to

severe COVID-19 and authorization is not limited to the medical conditions or factors listed above. More information about progression to severe disease can be found on the CDC page regarding COVID-19 risk in specific persons.

- **MOV is NOT authorized for use in patients:**
  - **Those under 18 years of age**
  - **Hospitalized due to COVID-19: Benefit of treatment with MOV has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19.** (*Note, patients with mild to moderate disease admitted to the hospital for another indication or solely for infection control purposes may be considered for treatment provided all other requirements have been met*). *Should a patient require hospitalization after starting treatment, they may complete the full 5 days course at the healthcare provider's discretion.*
  - **For longer than 5 consecutive days**
  - **As pre-exposure or post-exposure prophylaxis for prevention of COVID-19**
  - **MOV is not APPROVED for any use, including treatment of COVID-19**
- **Requirements for the prescribing provider:**
  - The provider must review the information contained within the "Fact Sheet for Patients and Caregivers" with the patient and/or caregiver prior to the patient receiving MOV, and must document that the patient/caregiver has been given an electronic or hard copy of the Fact Sheet.
  - The prescriber must inform the patient/caregiver of ALL of the following:
    - That MOV is an unapproved drug authorized under EUA
    - That there are no adequate approved products for treatment of mild-moderate COVID-19 in patients at high risk for progression to hospitalization or death
    - That there **ARE other currently authorized products for the same use as MOV (available at** Emergency Use Authorization | FDA)
    - That there are benefits and risks of MOV as outlined in the fact sheet
    - That Merck, Sharp & Dohme has established a pregnancy surveillance program
    - That 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 of MOV**, and that 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**
  - The prescriber **MUST ASSESS WHETHER A FEMALE OF CHILDBEARING POTENTIAL IS PREGNANT OR NOT, if clinically indicated, and given animal reproduction studies have suggested MOV may cause fetal harm when administered to pregnant individuals, additional requirements are in place when considering use in pregnancy, including:**
    - **The prescriber must communicate to the patient the known and potential risks of MOV during pregnancy (as outlined in the Fact Sheet for Patients and Caregivers)**
    - **If the decision is made to use MOV during pregnancy, the prescriber must DOCUMENT that the known and potential benefits and risks were discussed with the patient**
    - **The prescriber must document the patient was made aware that Merck, Sharp & Dohme has a pregnancy surveillance program (phone 877-888-4231, pregnancyreporting.msd.com) and if the pregnant individual agrees to participate in the surveillance program and allows the prescriber to disclose patient specific information, the prescriber must provide the patient's name and contact information to Merck.**
    - ***Note: pregnancy status does not need to be confirmed in patients who have undergone surgical sterilization, are using an intrauterine system or implant, or in whom pregnancy is not possible.***
  - The prescriber must report all medication errors and serious adverse events potentially related to MOV within 7 calendar days from the provider's awareness of the event. These should be reported through VA ADERS and per local policy. Serious adverse events include:
    - **Death**
    - **A life-threatening adverse event**
    - **Inpatient hospitalization or prolongation of hospitalization**
    - **Persistent or significant incapacity or disruption of ability to conduct normal life functions**
    - **Congenital abnormality / birth defect**
    - **Medical or surgical intervention was required to prevent death, a life-threatening adverse event, hospitalization, disability, or congenital abnormality**

Molnupiravir Mechanism of Action, Pharmacokinetics

What is MOV and how does it work?

- MOV is a an orally available nucleoside analog prodrug of an direct-acting antiviral which inhibits replication of multiple RNA viruses, including SARS-CoV-2, the viruses causing COVID-19.
- After cleaving of parent MOV in plasma, the active agent is phosphorylated intracellularly to the active triphosphate antiviral. The triphosphate moiety acts as a competitive substrate for virally encoded RNA-directed RNA polymerases, and is incorporated into viral RNA, disrupting viral genomic replication by causing an accumulation of mutations, also known as viral error catastrophe.
    - In vitro, EC_{50} values ranged from 0.67-2.66 uM in A-549 cells and 0.32 to 2.03 uM in Vero E6 cells, with similar activity seen against Alpha, Beta, Gamma and Delta variants.
    - No in vitro interaction on viral activity was noted when tested in combination with abacavir, emtricitabine, hydroxychloroquine, lamivudine, nelfinavir, **remdesivir**, ribavirin, sofosbuvir or tenofovir
    - MOV appears to have a high barrier to resistance, retaining activity against viruses with mutations resulting in resistance to remdesivir. No amino acid substitutions associated with resistance to NHC have been seen in Phase 2 trials.
    - In a small number of subjects, amino acid changes in the spike protein occurred at positions targeted by monoclonal antibodies and vaccines. The clinical and public health significance of these changes are unknown.

What are the pharmacokinetic (PK) properties of MOV?

- **Absorption:**
    - MOV is rapidly converted during absorption by the intestine and liver to N-hydroxycytidine (NHC) by carboxylesterases in serum with a median Tmax of NHC of approximately 1.5 hours
    - In patients, NHC C_{max} = 2330 ng/mL with a C_{12hr} of 31.1 ng/mL
    - A standard high fat meal did not impact MOV or NHC absorption or AUC, but was associated with a longer T_{max} and 35% reduction in C_{max}
    - Gastric acid reducers are not expected to have a meaningful impact on MOV absorption
- **Distribution**
    - NHC is rapidly taken up into cells and phosphorylated to N-hydroxycytidine triphosphate (NHC-TP), the pharmacologically active form of MOV
- **Metabolism**
    - MOV is rapidly converted to NHC, likely by widely distributed CES1 and CES2 carboxylesterases
    - MOV does not undergo significant hepatic metabolism
- **Excretion**
    - Only 3% of NHC is excreted in the urine
    - Effective half-life of NHC in plasma is 3.3 hours
- **Impact of organ dysfunction on PK**
    - Pharmacokinetics of NHC were not affected by age, sex, race, ethnicity or disease severity
    - Renal impairment is not anticipated to meaningfully impact PK of NHC and PK parameters in patients with mild or moderate renal impairment was comparable to those with normal renal function
    - Hepatic elimination is not expected to be a major route of NHC elimination, including on drug absorption

Dosing of MOV for mild-moderate COVID-19

How is MOV dosed for treatment of COVID-19?

- **The recommended dose is 800mg of MOV (given as four 200mg capsules) taken orally every 12 hours for 5 days.**
    - MOV can be taken with or without food
    - If the patient misses a dose of MOV within 10 hours of the time it is usually taken, they should take it as soon as possible and resume normal dosing. If missed by more than 10 hours, they should not take it and instead restart the normal dosing regimen with the next dose
    - If the patient requires hospitalization after starting MOV, they may complete the full 5-day course at the healthcare provider's discretion
- MOV should be given as soon as possible, and within 5 days of symptom onset
- Completion of the full 5-day course and continued isolation in accordance with public health recommendations are

important to maximize viral clearance and minimize transmission of SARS-CoV-2

- No dose adjustment is needed for renal or hepatic impairment or in geriatric patients

MOLNUPIRAVIR Efficacy for treatment of COVID-19 Infections

What efficacy data currently exist for treatment of COVID-19 with MOV?

- **EFFICACY SUMMARY**
  - Efficacy data for the use of MOV comes from several Phase 1 to Phase 3 clinical trials, including pivotal trials in hospitalized patients (MOVe-IN) and outpatients (MOVe-OUT), along with supplemental dose-finding, pharmacokinetic and virology Phase 1 and 2 trials.
  - The Phase 3 portion of MOVe-OUT provides clinical efficacy data from 1433 subjects receiving 800mg MOV or placebo twice daily for 5 days. Efficacy data was based on an interim analysis including 50% of the planned Phase 3 population, but after enrollment was complete. This included 385 who received MOV and 377 who received placebo. Top-line results from the full analysis population (n=1433) were also presented to the FDA.
  - **MOVe-OUT:**
    - MOVe-OUT is a double-blind, randomized, placebo-controlled trial in adults with mild to moderate COVID-19, with at least one risk factor for progression (age > 60 years, diabetes, obesity, chronic kidney disease, serious heart conditions, chronic obstructive pulmonary disease or active cancer).
    - Patients were required to have mild to moderate, laboratory-confirmed COVID-19 with symptom onset within 5 days of randomization.
    - **Vaccinated patients were excluded from the study.**
    - Primary outcome was the proportion of subjects who were hospitalized or died through day 29.
    - **Demographics (interim analysis):**
      - Baseline demographics were comparable between MOV and placebo
      - Mean age was 43 years with 17% over 60 years old. 49% were male, 57% were white, 5% Black and 3% Asian and 50% were Hispanic/Latino. The majority of patients enrolled came from Latin America or Europe.
      - Over 99% had at least one risk factor for progression to severe disease, including obesity (74%), age > 60 years (17%) and diabetes (16%).
      - Approximately 48% of subjects received MOV or placebo within 3 days of symptom onset. 18% had a positive SARS-CoV-2 antibody at baseline. The Delta, Mu and Gamma variants were most common at 58%, 20% and 11%, respectively based on viruses where sequencing data were available.
    - **Clinical efficacy results (Phase 3 MOVe-OUT)**
      - Primary efficacy data is provided for 709 subjects who received MOV and 699 who received placebo.
      - Through day 29, 6.8% of MOV subjects were hospitalized or died compared with 9.7% of those receiving placebo (n=699), a difference of - 3% (95% CI -5.9 to -0.1), p = 0.0218.
      - One death occurred in a MOV patient versus 9 with placebo.
      - While exploratory, results of subgroup analyses were generally consistent with the overall efficacy results, although in those subjects with a positive baseline antibody status, 3.7% of MOV and 1.4% of placebo subjects were hospitalized or died, compared with those who had a negative baseline antibody status, where the endpoint occurred in 7.2% of MOV and 12.3% of placebo subjects, for a difference of -5.1% (95% CI -8.8 to -1.6%)
  - **Virologic outcomes of MOV**
    - Phase 2 data found that decreases in viral RNA were greater with MOV 800mg q12h versus placebo in those presenting within 5 days of symptom onset. Virologic decline was similar to placebo in those with symptom onset > 5 days. A dose-dependent effect on viral load reduction and error rate, particularly at the 800mg dose of MOV, and particularly in those within 5 days of symptom onset.
    - **Virologic rebound: Post-treatment increases in viral shedding was seen in a subset of patients at day 10, 15 and/or day 29 with both MOV and placebo, and 1% of each group had evidence of recurrent symptoms coinciding with increased viral shedding, but this was not associated with an increase in hospitalization or death through day 29.**

.

Is MOV effective as a treatment for severe COVID-19 in hospitalized patients?

- The MOVe-IN trial was a phase 2/3 randomized, placebo controlled trial of MOV 200mg, 400mg, 800mg or placebo q12h for 5 days.
  - In the phase 2 portion of the trial, there was no difference with any dose versus placebo in the time to sustained recovery. In addition, a numerically higher proportion of patients receiving each MOV dose died (4.2-11%) versus placebo (2.7%). The deaths were largely related to COVID-19 and unlikely to be related to MOV.
  - As a result, the sponsor elected NOT to continue with the Phase 3 inpatient study. They suggested MOV was likely to be most effective if initiated early, and hospitalized patients generally present later in the course of the disease.
  - **MOV is NOT authorized or approved for the treatment of severe COVID-19 in hospitalized patients**
- **NOTE: MOLNUPIRAVIR is NOT a substitute for vaccination against COVID-19 and MOLNUPIRAVIR is NOT authorized as PRE-EXPOSURE OR POST-EXPOSURE PROPHYLAXIS for COVID-19**

MOLNUPIRAVIR Safety

What safety issues need to be considered when administering MOLNUPIRAVIR?

Adverse Event Data

- Overall, safety data are available for 710 study participants who received MOV throughout the Phase 3 MOVe-OUT study.
- In MOVeOUT, serious adverse events were reported in 7% of MOV and 10% of placebo treated subjects (most COVID-19 related). Adverse events leading to discontinuation occurred in 1% of MOV and 3% of placebo patients while adverse events leading to death were reported in < 1% of MOV and 2% of placebo patients.
- Adverse events that occurred in at least 1% of subjects were diarrhea (2%), nausea (1%) and dizziness (1%) which occurred at the same frequency in placebo subjects.
- No differences in grade 3 or 4 laboratory adverse events were reported between MOV and placebo and all occurred in 2% or less of each group.
- **During voluntary post-authorization reporting, the following have been identified: hypersensitivity, angioedema, erythema, rash and urticaria**

Contraindications: none

Warnings and Precautions

- **Embryofetal toxicity**: based on animal reproduction studies, MOV may cause fetal harm when administered to pregnant individuals.
  - **There are no human data on use in pregnancy, and therefore MOV is not recommended for use during pregnancy**
  - **IF a provider is considering MOV for a pregnant individual, all requirements noted above under EUA Indications and Requirements MUST be met.**
  - **MOV should only be prescribed to a pregnant individual after the prescribing provider has determined that the benefits would outweigh the risks for that individual patient**
  - More information on animal data in pregnancy is included in the section below
  - **Individuals of child-bearing potential**
    - Prior to initiating treatment with MOV, assess whether a woman of child-bearing potential is pregnant
      - Pregnancy does not need to be confirmed in patients who have undergone surgical sterilization, are currently using an intrauterine or implanted contraceptive device or in whom pregnancy is not possible
      - In all other women, assess whether the woman is pregnant using the first day of the last menstrual cycle (in those with regular cycles), or is using a reliable method of contraceptive consistently and correctly or has a negative pregnancy test. A pregnancy test is recommended in patients with irregular menstrual cycles, those unsure of the first day of the last menstrual cycle and in those not using consistent, reliable contraception
- **Hypersensitivity reactions, including anaphylaxis:** these have been reported during post-authorization with MOV. If signs of a clinically significant hypersensitivity reaction occur, immediately discontinue MOV and initiate appropriate supportive care.
- **Bone and cartilage toxicity:** MOV is not indicated for patients less than 18 years old as it may affect bone and cartilage growth (seen in studies in rats after repeated dosing).

- **Animal toxicology:** reversible, dose-related bone marrow toxicity affecting all hematopoietic cell lines was noted in dogs at less than human exposures. Mild decreases in peripheral blood cell and platelets were seen after 7 days and progressed to more severe changes by 14 days. These changes were not noted in rat studies at any dose or duration. **MOV is not indicated for more than 5 consecutive days.**

Drug-drug Interactions:

- No drug interactions have been identified based on limited available data.

Use in Pregnancy:

- There is a pregnancy surveillance program that monitors pregnancy outcomes in individuals exposed to MOV during pregnancy. The prescribing healthcare provider must document 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. Pregnant persons can also contact the registry directly through the same methods.

- **Risk summary in pregnancy:**
  - In an animal reproduction study, oral administration of MOV to pregnant rats during the period of organogenesis resulted in embryofetal lethality and teratogenicity at 8 times the human NHC (N4-hydroxycytidine) exposures at the recommended human dose (RHD) and reduced fetal growth at ≥ 3 times the human NHC exposure at the RHD.
    - Reported outcomes at 8 times the human NHC exposure at the RHD included post-implantation losses, malformations of the eye, kidney and axial skeleton and rib variations
    - At 3 times the human NHC exposure at the RHD, decreased fetal weight and delayed ossification were noted
    - No fetal toxicities were noted at doses less than the NHC exposure
  - Oral administration of MOV to pregnant rabbits during the period of organogenesis resulted in reduced fetal body weights at 18 times the human NHC exposure at the RHD
  - When considering MOV for a pregnant individual, the prescribing healthcare provider must communicate the known and potential benefits and the potential risks of using MOV during pregnancy to the pregnant individual, and it may only be prescribed after the prescriber has determined that the benefits outweigh the risks, and that all EUA requirements have been completed (see EUA Indications and Requirements above).
  - Importantly, there are maternal and fetal risks associated with untreated COVID-19 in pregnancy.
  - **Lactation:** There are no data on the presence of MOV or its metabolites in human milk. NHC was detected in the plasma of nursing pups from lactating rats administered MOV. It is unknown whether MOV has an effect on the breastfed infant or effects on milk production.
    - Based on the potential for adverse reactions in the infant, breastfeeding is not recommended during treatment with MOV and for 4 days after the final dose
- **Mutagenicity:** MOV was equivocal when tested for in vivo mutagenicity in one assay of reticulocytes and RBC, but not mutagenic in a 2nd assay of liver and bone marrow cells from transgenic rats administered MOV for up to 28 days.
  - **In contrast to somatic cells, germ cells (eggs and sperm) pass genetic information from generation to generation, and as a result, a planned study of male testicular germ cells is planned to assess the potential impact of MOV on offspring of treated males.**

Will the VA be monitoring for adverse events associated with MOLNUPIRAVIR?

- YES – given the limited safety data, vigilance in monitoring for unusual adverse events is critical. Physicians, nurses, pharmacists, and other healthcare providers should be monitoring patients closely for unusual clinical or laboratory events and report them.
- **All COVID-19 related ADEs are to be documented and reported to VA ADERS as a MedWatch report (a separate FDAMedWatch report is not required when submitted in VA ADERS)**
- VHA Center for Medication Safety will also be conducting prospective pharmacovigilance to identify potential adverse events and will report those to the FDA.

Other information about the MOLNUPIRAVIR EUA

What other things are important to know about MOLNUPIRAVIR or about the FDA EUA?

- Information on the FDA Emergency Use Authorization can be found on the FDA website: Letter of EUA for

MOLNUPIRAVIRImportant additional documents include the

- Fact sheet for healthcare providers for MOLNUPIRAVIR
- Fact sheet for patients and caregivers for MOLNUPIRAVIR
- Prescriber Checklist for MOLNUPIRAVIR – This checklist is available on the FDA website and may aid prescribers to ensure all required elements for the EUA are completed and documented
- Dear Healthcare Provider Letter for MOLNUPIRAVIR

How do I obtain MOLNUPIRAVIR for a patient with COVID-19 at my facility?

- MOV is being ordered centrally in the VA using the EUA SharePoint site
- Sites who have confirmed they are able to meet the administration requirements and wish to request MOV will place a request through the designated site, confirming their mailing address and phone number, pharmacy point(s) of contact
- Based on the requests from interested sites, product will be distributed equally to those sites and they will need to indicate when supply is received
- Once supply is on hand an in-line patient request form will be entered to ensure all required EUA tracking information is captured **PRIOR TO INITIATION OF TREATMENT**, including
  - ☐ Patient name, last 4 of SSN and date of birth, and date of positive COVID-19 test
  - ☐ Confirmation that the patient has laboratory confirmed mild to moderate COVID-19 diagnosis (MOLNUPIRAVIR is not authorized in patients who are hospitalized due to COVID-19)
  - ☐ Confirmation that administration will be within 5 days of symptom onset
  - ☐ Confirmation that the patient is at high risk for progression to severe disease per the updated CDC criteria
  - ☐ Confirmation that the other EUA treatments for mild-moderate COVID-19 are inaccessible or not clinically appropriate
  - ☐ Confirmation that the patient has been provided the "fact sheet for patients and caregivers" and that this is documented
  - ☐ Confirmation that if the patient is a female of childbearing potential, pregnancy status has been determined (unless the patient is surgically sterilized, has an intrauterine device or contraceptive implant or is unable to get pregnant). If the patient is not pregnant or is a male who is sexually active with a female of childbearing potential, the prescriber has explained that a reliable method of contraceptive should be used consistently during therapy and for up to 4 days after treatment (females) or 3 months after treatment (male partners of females of childbearing potential)
  - ☐ IF the provider decides to prescribe MOV during pregnancy, they must inform the patient that MOV is an unapproved drug, that there are no adequate approved products for treatment of mild-moderate COVID-19 in adults, that there ARE other products under EUA for the same use as MOV, that there are potential benefits and risks of use during pregnancy (as outlined in the patient fact sheet), that Merck has established a pregnancy surveillance program – **Consider use of the MOLNUPIRAVIR prescriber checklist to ensure all required elements are communicated and documented.**
  - ☐ Once all boxes are checked appropriately, an automatic approval notice will be generated with a link to a follow up form, on which the site will be asked to track the following
    - ☐ Date the drug was dispensed to the patient and the order number
    - ☐ Number of doses and dose dispensed
    - ☐ Lot numbers dispensed to the patient
    - ☐ If any adverse events occurred and if they were properly documented via local policy AND also VA ADERS
    - ☐ Certification that all information is accurate and complete. Records marked as complete will be subtracted from available stock and used for future allocation

References:

1. FDA Emergency use authorization for molnupiravir, 12/23/2021. Accessed 3/30/22

2. FDA EUA Fact Sheet for molnupiravir, 12/23/2021. Accessed 3/30/22

3. Merck Antimicrobial Drugs Advisory Committee Briefing document. Molnupiravir. 11/30/2021, Accessed 11/30/2021.

4. Merck Antimicrobial Drugs Advisory Committee Briefing Addendum. 11/30/21. Accessed 11/30/21.

5. FDA Briefing Document, Molnupiravir: Antimicrobial Drugs Advisory Committee. 11/30/21. Accessed 11/30/21

6. FDA Briefing Document Addendum, Molnupiravir. Antimicrobial Drugs Advisory Committee. 11/30/21. Accessed 11/30/21.

7. Bernal A, da Silva G, Musungaie DB, et al. Molnupiravir for oral treatment of COVID-19 in non-hospitalized patients. *N Engl J Med* 2021. Dec 16th. Doi: 10.10156/NEJMoa2116044