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GOVERNMENT OF THE DISTRICT OF COLUMBIA

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MURIEL BOWSER, MAYOR

January 6, 2022

Health Alert Notice for District of Columbia Health Care Providers
Use of Oral Antiviral Medications for COVID-19 Illness

SUMMARY

The U.S. Food and Drug Administration (FDA) has given two oral COVID-19 antiviral medications Emergency Use Authorization (EUA). These new oral antiviral medications Paxlovid and Molnupiravir will be available for health care providers to treat COVID-19 illness within the District in early January 2022. Only a very small number of treatment courses have been supplied to the District of Columbia by the U.S. Government, requiring that use be limited to those patients at greatest risk of severe illness. This Health Notice provides information on the patients for whom treatment with these antivirals is recommended and how to prescribe these medications.

BACKGROUND

The oral antiviral medications Paxlovid (Pfizer) and Molnupiravir (Merck) have recently been authorized by the FDA for limited use under Emergency Use Authorizations (EUAs), available here:

- For Paxlovid: fda.gov/media/155049/download
- For Molnupiravir: fda.gov/media/155053/download

According to information provided by the manufacturers, Paxlovid and Molnupiravir, when used for patients with mild to moderate illness, are 89% effective and 30% effective, respectively, in reducing the risk of hospitalization or death from COVID-19. More detail on the studies behind these claims is available at the links below:

- pfizer.com/news/press-release/press-release-detail/pfizer-announces-additional-phase-23-study-results
- merck.com/news/merck-and-ridgeback-biotherapeutics-provide-update-on-results-from-move-out-study-of-molnupiravir-an-investigational-oral-antiviral-medicine-in-at-risk-adults-with-mild-to-moderate-covid-19/

Each of these medications is to be used only for **non-hospitalized patients with mild-to-moderate illness who have a risk of developing severe illness**. Each is available as a five-day course of treatment, administered orally; according to the EUAs, treatment cannot be extended beyond five days. Fact sheets that provide greater detail about these drugs for prescribers can be found at COVID19oralRX.com and molnupiravir.com.

LIMTED AVAILABLITY

As of early January 2022, a very small number of treatment courses of these medications will be available to prescribers in Washington, DC. The number of treatment courses available is expected to increase during 2022. Because the availability is so limited, **DC Health is limiting the use of these medications to persons most likely to benefit from them based on age, the presence of other medical conditions, and/or the presence of immune deficiency.**

PATIENT ELIGIBILITY

Health care providers may prescribe Paxlovid or Molnupiravir for patients who meet the criteria summarized below. Note that the criteria are very similar for the two medications; however, Molnupiravir is contraindicated in pregnancy and for persons under 18 years of age. ***NOTE: Molnupiravir is authorized for use only when alternative COVID-19 treatments are not accessible or clinically appropriate.**

Criteria	Paxlovid (Pfizer)	Molnupiravir (Merck)
Residency status	Must be a DC resident	Must be a DC resident
Age	For use in patients 12 years or older weighing at least 40kg	For use in patients 18 years or older
Testing	Positive direct SARS-CoV-2	Positive direct SARS-CoV-2
Severity of disease	Mild to moderate COVID-19	Mild to moderate COVID-19
Duration of symptoms	Within 5 days of symptom onset	Within 5 days of symptom onset
Risk of progression	High risk* of progression to severe COVID-19, including hospitalization & death (See below for listing)	High risk* of progression to severe COVID-19, including hospitalization & death (See below for listing)
Alternative Treatments	N/A	Authorized when alternative COVID-19 treatment not accessible or clinically appropriate
Exclusions - Hospitalization	Not authorized for use with patients hospitalized for COVID-19	Not authorized for use with patients hospitalized for COVID-19
Exclusions - Prophylaxis	Not permitted for use as prophylaxis (pre-or post-exposure)	Not permitted for use as prophylaxis (pre-or post-exposure)
Exclusions - Pregnancy	N/A for Paxlovid	Pregnancy (Fetal-Embryo Toxicity)
Additional Exclusions per EUA	Contraindications in EUA	Contraindications in EUA

*For the purposes of eligibility for prescription of these oral therapeutics, DC Health considers persons to be at high risk of progression to severe COVID-19 illness if they meet any the following combinations of age and pre-existing medical conditions.

- **Age ≥ 75**, or
- **Age 65 – 74 and having any of the following conditions**:
  - Cancer
  - Chronic kidney disease
  - Chronic obstructive pulmonary disease
  - Obesity
  - Heart conditions
  - Smoker (current)
  - Sickle cell disease
  - Type 2 diabetes mellitus
- **Age > 12 (for Paxlovid) or >18 (for Molnupiravir) and <u>severely</u> immunocompromised,** such as persons:
  - Actively receiving cancer chemotherapy
  - On immunosuppressive treatment for organ transplant
  - With untreated HIV infection **and** CD4 counts below 50 cells/mm^3
  - With severe combined immunodeficiency syndrome

<u>HOW TO PRESCRIBE</u>

Both medications should be started as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.

- **Paxlovid** is supplied as a package that includes nirmatrelvir tablets (150 mg) and ritonavir tablets

(100 mg). Two tablets of nirmatrelvir (total dose 300 mg) and one tablet of ritonavir should be taken twice daily for 5 days. More details on prescribing, including contraindications and adverse effects, are provided on the fact sheet for health care providers available at COVID19oralRX.com.

- **Monupiravir** is supplied as 200 mg capsules. Four capsules (800 mg) are to be taken orally every 12 hours for 5 days. More details on prescribing, including contraindications and adverse effects, are provided on the fact sheet for health care providers available at molnupiravir.com.

Paxlovid appears more effective than Molnupiravir, but there are fewer doses of Paxlovid available. You may not know at the time of prescription which of these medications is available at the pharmacy. You may choose to give eligible patients prescriptions for both medications, ***giving them instructions to fill only one prescription.*** If both medications are available, your patient should fill the prescription for Paxlovid. If only Molnupiravir is available, the patient should fill the prescription for Molnupiravir.

PHARMACY AVAILABLITY

While supplies of these medications are extremely limited, Paxlovid and Molnupiravir will be distributed through a limited number of retail pharmacies located strategically across Washington, DC. As of early January 2022, prescriptions for these medications can be filled only at the Safeway pharmacy locations listed below and will be available at additional locations in the near future. This guidance will be updated as additional pharmacy locations are added. Inventory levels may vary and total courses available are based on overall State and jurisdiction allocations as determined by the U.S. Government.

Store Name	Address	Phone Number
Safeway #2912	1855 Wisconsin Ave, NW, Washington DC 20007	(202) 333-6048
Safeway #3217	415 14th Street SE, Washington DC 20003	(202) 920-5875
Safeway #4270	1601 Maryland Ave., NE, Washington DC 20002	(202) 398-6900

TESTING

Treatment with either Paxlovid or Molnupiravir should begin within five (5) days from symptom onset and patients must have a positive direct SARS-CoV-2 test result. These test results can include rapid antigen tests or PCR tests. Within the District, testing locations can be found on the DC Health coronavirus website at coronavirus.dc.gov/testing.

ADDITIONAL RESOURCES

- **Emergency Use Authorization**
  - Paxlovid:
    - fda.gov/media/155049/download
  - Molnupiravir:
    - fda.gov/media/155053/download
- **Patient Fact Sheets**
  - Paxlovid:
    - covid19oralrx-patient.com/files/Final-EUA-Fact-sheet-for-Patients-Parents-and-Caregivers-COVID-19-Oral-Antiviral.pdf
  - Molnupiravir:
    - merck.com/eua/molnupiravir-patient-fact-sheet-english.pdf

For questions regarding COVID-19 Therapeutics, please contact DC Health at:
Phone: 1-855-363-0333 (M-Sa 9:00am – 5:30pm) | Email: covid.therapeutics@dc.gov