



April 29, 2022

<u>Health Alert Notice for District of Columbia Health Care Providers</u> Use of Oral Antiviral Medications for COVID-19 Illness - Updated

SUMMARY

The U.S. Food and Drug Administration (FDA) has given two oral COVID-19 antiviral medications Emergency Use Authorization (EUA). The oral antiviral medications Paxlovid and Molnupiravir are available for health care providers to treat COVID-19 illness within the District. 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 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:

- <u>pfizer.com/news/press-release/press-release-detail/pfizer-announces-additional-phase-23-study-results</u>
- merck.com/news/merck-and-ridgeback-biotherapeutics-provide-update-on-results-from-move-outstudy-of-molnupiravir-an-investigational-oral-antiviral-medicine-in-at-risk-adults-with-mild-tomoderate-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. More information about potential drug interactions is available at covid19treatment-guidelines.nih.gov.

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)
Age	For use in patients 12 years or	For use in patients 18 years or
	older weighing at least 40kg	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	Within 5 days of symptom
	onset	onset





	High risk* of progression to	High risk* of progression to
Risk of progression	severe COVID-19, including	severe COVID-19, including
	hospitalization & death	hospitalization & death
		Authorized when alternative
A14 4° 75 4	N/A	COVID-19 treatment not
Alternative Treatments		accessible or clinically
		appropriate
	Not authorized for use with	Not authorized for use with
Exclusions - Hospitalization	patients hospitalized for	patients hospitalized for
	COVID-19	COVID-19
	Not permitted for use as	Not permitted for use as
Exclusions - Prophylaxis	prophylaxis (pre-or post-	prophylaxis (pre-or post-
	exposure)	exposure)
		Not recommended for use
Exclusions - Pregnancy	N/A for Paxlovid	during pregnancy (Fetal-
,		Embryo Toxicity)
Additional Exclusions per	Contraindications in EUA	Contraindications in EUA
EUA	Contraindications in EUA	Contramulcations 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 are:

- Age \geq 65, or
- Age > 12 (for Paxlovid) or >18 (for molnupiravir) and have any of the conditions that increase the risk of severe illness listed by the CDC at cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

HOW TO PRESCRIBE

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. Additionally, on April 14, 2022, the FDA updated the Paxlovid EUA to authorize an additional dose pack presentation of Paxlovid with appropriate dosing for patients within the scope of this authorization with moderate renal impairment. 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.

PHARMACY AVAILABLITY

Paxlovid and Molnupiravir are distributed through selected pharmacies in Washington, DC including retail pharmacies and healthcare facility outpatient pharmacy locations.

Retail Pharmacy locations:

Store Name	Address	Phone Number
Giant Pharmacy #378	1345 Park Road, NW, Washington DC, 20010	(202)-777-1078
Giant Pharmacy #384	1535 Alabama Ave, SE, Washington DC, 20032	(202)-610-6450





Safeway #1276	6500 Piney Branch Rd, NW, Washington DC, 20012	(202) 723-5612
Safeway #1445	2845 Alabama Ave, SE, Washington DC, 20020	(202)-575-7527
Safeway #2737	490 L Street, NW, Washington DC, 20001	(202) 719-2439
Safeway #2808	3830 Georgia Ave, NW, Washington DC, 20011	(202) 722-4067
Safeway #2892	1100 4th Street, SW, Suite 150, Washington DC 20024	(202) 719-2500
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 #4202	1747 Columbia Road, NW, Washington DC, 20009	(202) 667-2080
Safeway #4270	1601 Maryland Ave, NE, Washington DC 20002	(202) 398-6900
Safeway #4832	5545 Connecticut Ave, NW, Washington DC, 20015	(202) 364-0320

Healthcare facility outpatient pharmacy locations:

Healthcare Facility	Address
<u>Name</u>	
The GW Medical Faculty Associates	2150 Pennsylvania Ave, NW, Ste 6A-403 Washington DC, 20037
Kaiser Permanente	700 2nd Street, NE,
Capitol Hill	Washington DC 20002
Kaiser Permanente Northwest	2301 M Street NW, Suite 200, Washington DC, 20037
MedStar Pharmacy at	3800 Reservoir Rd, NW,
Georgetown University Hospital	Washington DC, 20070
MedStar Pharmacy at	106 Irving Street, NW,
Washington Hospital	Suite 1200,
Center	Washington DC, 20010

Additionally, oral COVID-19 antiviral medication is available at Test to Treat program locations across the District (aspr.hhs.gov/TestToTreat/Pages/default.aspx). The test to treat program is an additional pathway for fast access to lifesaving COVID-19 treatments and can be found online at a web-based site locator (covid-19-test-to-treat-locator-dhhs.hub.arcgis.com/) available to make it easier to find Test to Treat locations.





Those who may have difficulty accessing the internet or need additional support locating a Test to Treat site can call <u>1-800-232-0233</u> (TTY <u>1-888-720-7489</u>) to get help in English, Spanish, and more than 150 other languages – 8am to midnight ET, 7 days a week. The Disability Information and Access Line (DIAL) is also available to specifically help people with disabilities access services at <u>1-888-677-1199</u>, Monday-Friday from 9:00am to 8:00pm or via email at <u>DIAL@usaginganddisability.org</u>.

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
 - o Paxlovid:
 - fda.gov/media/155049/download
 - Molnupiravir:
 - fda.gov/media/155053/download
- Patient Fact Sheets
 - o Paxlovid:
 - covid19oralrx-patient.com/files/Final-EUA-Fact-sheet-for-Patients-Parents-and-Caregivers-COVID-19-Oral-Antiviral.pdf
 - o 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