

December 27, 2021

Dear Colleague,

We write to alert you that last week, the US Food and Drug Administration (FDA) gave two oral COVID-19 antiviral medications Emergency Use Authorizations (EUA).

Please see below for descriptions of each medication and guidance.

Paxlovid (Pfizer), an oral antiviral medication, received an EUA from the FDA on December 22, 2021. The drug is indicated for the treatment of COVID-19 among patients ages 12 and over who weigh 40 kg or more, test positive for COVID-19, are within 5 days of the onset of symptoms, have mild to moderate symptoms, and do not require hospitalization but are at risk for progression to severe disease based on underlying conditions. It is taken as three (3) pills twice a day for five (5) days, and the full course is required to achieve the benefit of the medication.

The U.S. Government has purchased 10 million courses of Paxlovid and will begin distribution to jurisdictions on or about December 27, 2021. The initial two-week allocation to Maryland is 960 courses. The U.S. Government expects larger allocations of doses nationwide in January 2022 and further expansion thereafter.

Molnupiravir (Merck), an oral antiviral medication, received an EUA from the FDA on December 23, 2021. The drug is indicated for the treatment of COVID-19 among patients ages 18 and over who weigh 40 kg or more, test positive for COVID-19, are within five (5) days of the onset of symptoms, have mild to moderate symptoms, and do not require hospitalization, but are at risk for progression to severe disease based on underlying conditions and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate. The medication is not indicated during pregnancy. It is taken as four (4) pills twice a day for five (5) days, and the full course is required in order to achieve the benefit of the medication.

The U.S. Government will allocate 300,000 courses of this medication nationally and will begin a pro rata distribution to jurisdictions on or about December 27, 2021. The initial two-week allocation to Maryland is 4,500 courses. The U.S. Government expects allocations to continue on a bi-weekly basis.

Prioritization

With the initial supply, the Maryland Department of Health (MDH) recommends that providers prioritize the use of these medications to the highest-risk patients. In order to assist in prioritization, MDH recommends providers follow the National Institute of Health <u>guidance</u> developed for prioritization of monoclonal antibodies and that recommends treating the highest-risk patients first.

Testing

In order to begin treatment within the recommended five (5) day window from onset of symptoms, early COVID-19 testing and rapid return of results are critical. Diagnosis of COVID-19 symptomatic patients with rapid antigen tests has been demonstrated to be both

sensitive and specific.¹ These tests can be done in provider's offices, at testing sites, or by home testing kits. Additional information on office-based testing can be found here.

Prescribing

Physicians, Certified Registered Nurse Practitioners, and Physician Assistants are the only categories of providers permitted to prescribe this medication. The oral antiviral medication is not a controlled substance; however, prescribers are required to add their United States Drug Enforcement Administration (DEA) number to the prescription to assist in tracking and record-keeping of the medication. If a prescriber does not have a DEA number, one may substitute an NPI number.

Pharmacy Locations and Logistics

Due to the initial, small size of the allocation to Maryland, the medication will be provided to a limited number of pharmacies located strategically across the State. The list of the pharmacies, addresses, and their contact numbers can be found below. All of these pharmacies have both drive-through and home-delivery capabilities. The home-delivery service may have distance limitations and associated charges.

In order to avoid sending prescriptions and patients to a pharmacy that has depleted its stock, the State will provide an estimate of inventory by site posted on the MedChi website twice a day. The twice per day update does still allow for gaps of time during which stock may have been depleted. In addition, Walgreens Pharmacy will provide a phone number that will allow providers to get real-time inventory information for each pharmacy in the near future. You are encouraged to either visit the MedChi website or to call the local Walgreens Pharmacy to ensure availability prior to sending a prescription.

EUA Resources

For Paxlovid:

- 1. Paxlovid EUA
- 2. Provider Information sheet
- 3. Patient and Caregiver Information sheet

For Molnupiravir:

- 1. <u>Molnupiravir EUA</u>
- 2. Provider information Sheet
- 3. Patient and Caregiver information Sheet

Other Resources

There will be a *Testing and Therapeutics Special Covid Update Webinar*, on Wednesday 12/29 starting at 5:00 PM (<u>registration link</u>).

a. The webinar will include time for Q&A and slides, and a recording will be sent out to all registrants following the webinar.

Availability

¹ Dinnes J, Deeks JJ, Berhane S, et al. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Cochrane Database Syst Rev. 2021;3(3):CD013705. Published 2021 Mar 24. doi:10.1002/14651858.CD013705.pub2

Due to the initial, small size of the state allocation, the medication will be provided to a limited number of pharmacies located strategically across the State. (Please see the attached Appendix A).

In order to avoid sending prescriptions and patients to a pharmacy that has depleted its stock, the State will provide an estimate of inventory by site posted on the <u>MedChi website</u> twice a day.

Sincerely,

Howard Haft, MD, MMM, CPE, FACPE Senior Medical Advisor

Maryland Primary Care Program (MDPCP)

Appendix A: Walgreens Participating Locations, 12/27/2021

Please note inventory levels may change and total courses available are based on allocation from the Federal Government.

Store Name	Address	County	Allocated Courses of Molnupiravir	Allocated Courses of Paxlovid
Walgreens 17857	101 Bishop Murphy Dr, Frostburg, MD 21532	Allegany	140	40
Walgreens		- 3 -		-
12266	209 N 3rd St, Oakland, MD 21550	Garrett	140	40
Walgreens	17703 Virginia Ave, Hagerstown, MD			
13892	21740	Washington	140	40
Walgreens 10402	11745 Rousby Hall Rd, Lusby, MD 20657	Calvert	140	40
Walgreens 10063	6300 Crain Hwy, La Plata, MD 20646	Charles	140	40
Walgreens 17917	12701 Laurel Bowie Rd, Laurel, MD 20708	Prince George's	140	40
Walgreens 10905	640 Sunburst Hwy, Cambridge, MD 21613	Dorchester	140	40
Walgreens 15284	900 N Washington St, Baltimore, MD 21205	Baltimore City	160	40
Walgreens 12130	909 Mount Hermon Rd, Salisbury, MD 21804	Wicomico	140	40
Walgreens 6779	9616 Harford Rd, Baltimore, MD 21234	Baltimore County	140	40
Walgreens 17944	110 Mitchells Chance Rd, Edgewater, MD 21037	Anne Arundel	140	40
Walgreens 11949	5585 Twin Knolls Rd, Columbia, MD 21045	Howard	140	40
Walgreens 19380	6970 Crestwood Boulevard, Frederick, MD 21703	Frederick	140	40
Walgreens 10977	301 E Pulaski Hwy, Elkton, MD 21921	Cecil	140	40
Walgreens 11763	701 Washington Ave, Chestertown, MD 21620	Kent	140	40
Walgreens 19966	19927 Century Blvd, Germantown, MD 20874	Montgomery	140	_
Walgreens 11057	2440 Centreville Rd, Centreville, MD 21617	Queen Anne's	140	_
Walgreens 11169	950 Beards Hill Rd, Aberdeen, MD 21001	Harford	140	-
Walgreens 13457	500 Meadow Creek Dr, Westminster, MD 21158	Carroll	140	-
Walgreens 5408	1300 E North Ave, Baltimore, MD 21213	Baltimore City	140	_

Walgreens 17672	30283 Triangle Dr, Charlotte Hall, MD 20622	Saint Mary's	140	-
Walgreens 19451	21 Denton Plaza, Denton, MD 21629	Caroline	140	_
Walgreens 9967	8174 Ocean Gtwy, Easton, MD 21601	Talbot	140	-
Walgreens 11951	11085 Cathell Road, Berlin, MD 21811	Worcester	140	_
Walgreens 13893	1631 Dual Hwy, Hagerstown, MD 21740	Washington	140	_
Walgreens 17333	1000 Key Parkway, Frederick, MD 21702	Frederick	140	-
Walgreens 19427	403 George Claus Blvd, Severn, MD 21144	Anne Arundel	140	-
Walgreens 9632	2970 Shasho Pl, Waldorf, MD 20603	Charles	140	_
Walgreens 10076	2560 Quarry Lake Dr, Baltimore, MD 21209	Baltimore County	140	_
Walgreens 11064	21400 Zeeman Rd, Rock Hall, MD 21661	Kent	140	_
Walgreens 17859	5741 Silver Hill Rd, District Heights, MD 20747	Prince George's	140	-
Walgreens 9927	735 S Salisbury Blvd, Salisbury, MD 21801	Wicomico	140	_
Total			4,500	600