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To: Health Care Providers and Health Care Facilities
From: New York State Department of Health

COVID-19 ORAL ANTIVIRAL TREATMENTS AUTHORIZED AND SEVERE SHORTAGE OF ORAL ANTIVIRAL AND MONOCLONAL ANTIBODY TREATMENT PRODUCTS

Summary:

- Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).
 - Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 when started early after symptom onset.
 - Paxlovid is the preferred product and is available for patients age 12 years and older.
 - Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA- authorized COVID-19 treatment options are not accessible or clinically appropriate.
- At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.
 - There will be a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV beginning 1/3/2022.
- Adhere to [New York State Department of Health \(NYS DOH\) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.](#)

The announcement is to make you aware of information about available COVID-19 outpatient therapeutics, including newly authorized oral antiviral treatments.

While the availability of oral antivirals for treatment of COVID-19 is an important milestone, it comes at a time of a significant surge in cases and reduced effectiveness of existing therapeutics due to the omicron variant, which is now the predominant variant nationally and estimated by the [Centers of Disease Control and Prevention \(CDC\)](#) to account for over 90% of cases in New York. Supplies of oral antivirals will be extremely limited initially, and there is now only one monoclonal antibody product that is effective for treatment of infection caused by the omicron variant. While supplies remain low, adhere to the [NYS DOH guidance on prioritization of anti-SARS-CoV-2 therapies for treatment and prevention of severe COVID-19](#) and prioritize therapies for people of any eligible age who are [moderately to severely immunocompromised](#) regardless of vaccination status or who are age 65 and older and not fully vaccinated with at least one [risk factor for severe illness](#).

COVID-19 Oral Antiviral Treatment

The FDA authorized the first oral antiviral therapies, Paxlovid from Pfizer and molnupiravir from Merck, to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, regardless of vaccination status. The oral antivirals work by interfering with several steps in the reproductive process of SARS-CoV-2 to prevent efficient replication of the virus in host cells. The U.S. Department of Health and Human Services (HHS) provides oral antivirals at no cost to patients.

Paxlovid is the preferred product, and molnupiravir can be considered for patients age 18 years and older for whom alternative FDA-authorized COVID-19 treatment options are not accessible or clinically appropriate. Prior to initiating treatment, providers and patients should carefully consider the known and potential risks and benefits. Limited supply will require providers to prioritize treatment for patients at highest risk for severe COVID-19 until more product becomes available.

[Paxlovid](#) clinical trials among 2,246 high-risk patients showed an 88% reduction in the risk for hospitalization and death among people taking paxlovid compared to those taking placebo. Paxlovid is a combination treatment with PF-07321332 (or nirmatrelvir) and ritonavir. PF-07321332 inhibits the main protease of SARS-CoV-2 virus, the 3CL-like protease, that impedes synthesis of other non-structural proteins and ultimately inhibits viral replication. Ritonavir is a protease inhibitor (also used in HIV treatment) that acts as a pharmacokinetic enhancer of protease inhibitors.

[Molnupiravir](#) clinical trials among 1,433 high-risk patients showed a 30% reduction in the risk for hospitalization and death among people taking molnupiravir compared to those taking placebo. Molnupiravir is the pro-drug of a nucleoside analog that competes with the viral RNA polymerase and induces RNA mutations that ultimately have an antiviral effect.

Eligibility

Oral antiviral treatment is authorized for patients who meet all the following criteria:

- Age 12 years and older weighing at least 40 kg (88 pounds) for Paxlovid, or 18 years and older for molnupiravir
- Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate
- Have [mild to moderate COVID-19 symptoms](#)
 - Patient cannot be hospitalized due to severe or critical COVID-19
- Able to start treatment within 5 days of symptom onset
- Have a medical condition or other factors that increase their risk for severe illness.
 - Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19

Under the authorizations, paxlovid and molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under New York State law to prescribe drugs in the therapeutic class to which paxlovid and molnupiravir belong (i.e., anti-infectives).

For Paxlovid only:

- Therapy is contraindicated for patients (1) with a history of clinically significant hypersensitivity reactions to its active ingredients or any other components of the product; (2) treating with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or (3) treating with drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the [Paxlovid Fact Sheet for Providers, Section 7](#).
- Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.
- Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

- Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.
- 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.
- For more details, please refer to molnupiravir [Fact Sheet for Providers](#).

Clinical Considerations

Treatment is most effective when given as soon as possible and no more than 5 days after symptom onset. High-risk patients who present within 6 to 10 days of symptoms onset should be referred for monoclonal antibody therapy.

The most common side effects reported during treatment and within 14 days after the last dose of molnupiravir were mild or moderate diarrhea, nausea, and dizziness. For Paxlovid, mild or moderate dysgeusia, diarrhea, hypertension, and myalgia were reported.

Oral antivirals are not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19. Oral antivirals should not be used for longer than 5 consecutive days.

Referring Patients for Oral Antivirals Outside of NYC

To ensure equitable access to oral antivirals, the New York State Department of Health has worked in partnership with local jurisdictions to identify 1-2 pharmacies within each jurisdiction (where possible). As supplies increase, additional pharmacies will be added. A list of participating pharmacies is provided in Appendix A at the end of this message.

Product is expected to ship on Tuesday 12/28/2021 and the earliest orders will be able to be filled is estimated to be Wednesday 12/29/2021. Please contact the local pharmacy to confirm availability or if your local pharmacy is Walmart, go to www.walmart.com/covidmedication to inquire about product availability at each store.

Referring Patients for Oral Antivirals in NYC

To ensure equitable access to oral antivirals, the NYC Department of Health and Mental Hygiene (Health Department) has partnered with Alto Pharmacy, a pharmacy delivery service. At this time, this is the only way NYC patients can receive oral antivirals. As supplies increase, additional pharmacies will be added.

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and through a language line in Russian, Mandarin, Vietnamese, Arabic, and Korean. Prescriptions confirmed by 5 p.m. on weekdays or 1p.m. on weekends will be delivered the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

Providers who would like to automatically have molnupiravir substituted when Paxlovid is unavailable must submit two prescriptions, one for each medication, with a comment in the notes section of the molnupiravir prescription which reads "to be used in case Paxlovid prescription cannot be filled because of supplies limitation". Substituting with molnupiravir can only be done for patients meeting eligibility criteria and with no contraindications for either product.

Changes to Monoclonal Antibody Use

At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody therapeutic that is expected to be effective against the omicron variant of SARS-CoV-2. Supplies of Sotrovimab are extremely limited and providers should adhere to [NYS DOH prioritization guidance](#).

As of [December 23, 2021](#), there is a pause on further allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV beginning 1/3/2022. Bamlanivimab with etesevimab and REGEN-COV do not retain activity against omicron. NYC providers should refer to NYC's [Letter to Providers: Omicron and Monoclonal Antibodies](#). Monoclonal antibody treatment can no longer be used as post-exposure prophylaxis.

Please continue to monitor our website regularly for updated guidance, including on treatment supply and prioritization: [COVID-19 Monoclonal Antibody \(mAb\) Therapeutics: Information for Providers | Department of Health \(ny.gov\)](#).

Appendix A: List of Participating Pharmacies outside of New York City by County

County Name	Store #	Store Name	City	Zip
Albany	417	CVS	ALBANY	12205
Albany	2702	CVS	COLONIE	12205
Albany		CENTRAL AVE PHARMACY	ALBANY	12206
Broome	1835	Walmart	VESTAL	13850
Cayuga	62	Kinney Drugs	AUBURN	13021
Cayuga	73	Kinney Drugs	MORAVIA	13118
Chautauqua	10870	Rite Aid	JAMESTOWN	14701
Chautauqua	10811	Rite Aid	DUNKIRK	14048
Chemung	10880	Rite Aid	HORSEHEADS	14845
Chemung	260	Rite Aid	ELMIRA	14901
Chenango	2120	Walmart	NORWICH	13815
Clinton		Condo Pharmacy	PLATTSBURGH	12901
Clinton		Cornerstone Drug & Gift	ROUSES POINT	12979
Columbia	242	CVS	HUDSON	12534
Cortland	7	Kinney Drugs	CORTLAND	13045
Delaware	19432	Walgreens	STAMFORD	12167
Dutchess	418	CVS	POUGHKEEPSIE	12601
Dutchess		Beekman pharmacy	POUGHQUAG	12570
Erie		Tile Pharmacy	CHEEKTOWAGA	14225
Erie		Kenmore Rx Center	KENMORE	14217
Erie		Wanakah Pharmacy	HAMBURG	14075
Erie		Larwood Pharmacy, Inc.	EAST AURORA	14052
Erie		Cy's Elma Pharmacy	ELMA	14059
Erie	3288	Walgreens	BUFFALO	14215
Essex	95	Kinney Drugs	LAKE PLACID	12946
Essex		Moriah Pharmacy	PORT HENRY	12974
Essex		Willsboro Pharmacy	WILLSBORO	12996
Franklin	10591	Walgreens	MALONE	12953
Fulton	18296	Walgreens	JOHNSTOWN	12095
Genesee	10807	Rite Aid	BATAVIA	14020
Hamilton		NATHAN LITTAUER HOSPITAL	SPECULATOR	12164
Herkimer	27	Kinney Drugs	ILION	13357
Jefferson		BOLTONS PHARMACY	WATERTOWN	13601
Jefferson	42	Kinney Drugs	ALEXANDRIA BAY	13607
Lewis	20	Kinney Drugs	LOWVILLE	13367
Livingston	5072	CVS	DANSVILLE	14437
Madison		Dougherty Pharmacy	MORRISVILLE	13408
Madison	46	Kinney Drugs	CHITTENANGO	13037

County Name	Store #	Store Name	City	Zip
Monroe	5123	CVS	BROCKPORT	14420
Monroe	831	CVS	WEBSTER	14580
Monroe	10512	Walgreens	ROCHESTER	14621
Montgomery	25	Kinney Drugs	ST. JOHNSVILLE	13452
Nassau	997	CVS	GLEN COVE	11542
Nassau	2028	CVS	HEMPSTEAD	11550
Nassau	1084	CVS	FREEMPORT	11520
Niagara	10817	Rite Aid	LOCKPORT	14094
Niagara	3600	Rite Aid	NIAGARA FALLS	14301
Oneida	639	Rite Aid	UTICA	13502
Oneida	610	Rite Aid	ROME	13440
Oneida		Bassett Medical Center OP Pharmacy	COOPERSTOWN	13326
Onondaga	43	Kinney Drugs	BALDWINVILLE	13027
Onondaga	79	Kinney Drugs	LIVERPOOL	13088
Onondaga	108	Kinney Drugs	SYRACUSE	13206
Onondaga	64	Kinney Drugs	EAST SYRACUSE	13057
Ontario	10846	Rite Aid	GENEVA	14456
Ontario	10842	Rite Aid	CANANDAIGUA	14564
Orange	10688	CVS	NEWBURGH	12550
Orange	2908	CVS	MONROE	10950
Oswego		Wayne Drug- Oswego	OSWEGO	13126
Otsego	2262	Walmart	ONEONTA	13820
Putnam		COMMUNITY PHARMACY INC	BREWSTER	10509
Putnam	5054	CVS	CARMEL	15012
Rensselaer	906	CVS	TROY	12182
Rensselaer	2137	CVS	WYNANTSKILL	12198
Rockland	2205	CVS	SPRING VALLEY	10977
Saratoga	10384	Walgreens	WILTON	12866
Saratoga	5046	CVS	CLIFTON PARK	12065
Schenectady	2340	CVS	SCHENECTADY	12304
Schenectady	5385	CVS	SCOTIA	12302
Schoharie	7326	CVS	COBLESKILL	12043
Schuyler	3221	Walmart	WATKINS GLEN	14891
Seneca	65	Kinney Drugs	SENECA FALLS	13148
St. Lawrence	1	Kinney Drugs	GOUVERNEUR	13642
St. Lawrence		The Medicine Place-KimRos Inc.	OGDENSBURG	13669
St. Lawrence		Adk Pharmacy COVID-19	STAR LAKE	13690
Steuben	2326	Walmart	HORNELL	14830
Steuben	2992	Walmart	PAINTED POST	14810

County Name	Store #	Store Name	City	Zip
Suffolk	3099	CVS	BAY SHORE	11706
Suffolk	6026	CVS	RIVERHEAD	11901
Suffolk	1271	CVS	ROCKY POINT	11778
Suffolk	2961	CVS	HUNTINGTON STATION	11746
Sullivan		Rock Hill Healthmart Pharmacy	ROCK HILL	12775
Sullivan		K & K Pharmacy	LIBERTY	12754
Tompkins	80	Kinney Drugs	ITHACA	14850
Ulster	8945	CVS	KINGSTON	12401
Ulster	323	CVS	SAUGERTIES	12477
Warren	419	CVS	QUEENSBURY	12804
Washington	2685	CVS	HUDSON FALLS	12839
Wayne	66	Kinney Drugs	LYONS	14489
Westchester	5048	CVS	PEEKSKILL	10566
Westchester	5350	CVS	PORT CHESTER	10573
Westchester	4539	CVS	YONKERS	10701
Wyoming		Sinclair Pharmacy	WARSAW	14569
Yates	442	Rite Aid	PENN YAN	14527