



February 20, 2024

TO: Healthcare Providers, Hospitals, Local Health Departments, Family Planning Providers, Emergency Rooms, Community Health Centers, College Health Centers, Community-Based Organizations, Internal Medicine, Family Medicine, Pediatric, Adolescent Medicine, Dermatology, Infectious Disease, Primary Care Providers, Pharmacists, Nursing Homes, and Adult Care Facilities

FROM: New York State Department of Health (NYSDOH)

HEALTH ADVISORY: COVID-19 ANTIVIRAL TREATMENT UNDERUTILIZATION AND CHANGES IN HOW TO ACCESS MEDICATIONS WITH COMMERCIALIZATION OF ORAL ANTI-VIRALS

- **COVID-19 antivirals remain underutilized in high-risk populations. Recent data from the National Institutes of Health (NIH) show that only 10% of individuals with COVID-19 who are at high risk for severe COVID-19 are treated. ¹**
- **Individuals at high risk for severe COVID-19 include those aged 50 and older, those who are unvaccinated, and those with a range of health conditions including diabetes, heart disease and obesity. ²**
- **Antiviral therapy for COVID-19 infection reduces the risk of hospitalization and death in individuals at high risk of progression to severe disease from COVID-19.³**
- **Oral antivirals remain active against current circulating strains of SARS-CoV-2, the virus causing COVID-19.**
- **COVID-19 oral antiviral treatments have transitioned from US government-managed purchase and distribution to the commercial market with changes in how patients can access medications.**
- **Several programs have been developed to ensure access to antiviral medications at low or no cost to patients (please see table below).**
- **Home Test-to-Treat funded by the federal government offers evaluation and treatment regardless of insurance status.**

SARS-CoV-2 (the virus that causes COVID-19) continues to circulate in New York City and New York State.

- Statewide data are available here for [COVID-19](#),
- New York City specific data can be accessed here: [SARS-CoV-2 \(COVID-19\)](#).

Those at high risk of severe outcomes due to COVID-19 infection include patients who are older (i.e., those aged >50 years and especially those aged ≥65 years) or who have certain medical

conditions (e.g., diabetes, heart disease, obesity), including moderate to severe immunocompromising conditions would most benefit from anti-viral treatment. ² Two oral anti-viral options currently available are **nirmatrelvir/ritonavir (Paxlovid) and molnupiravir (Lagevrio)**.

The Department reminds providers to treat patients with COVID-19 as they would any other disease. Patients with COVID-19 do need to be evaluated promptly either in person, or via tele-health. Providers, as with a patient with any other disease, should consider the risks and benefits of treatment and make an appropriate clinical judgement regarding treatment. Providers who refuse consideration of treatment without considering the risks and benefits of treatment are advised that they are not meeting the minimum standard of care.

- **Antivirals reduce the risk of hospitalization and death** and are recommended for patients with COVID-19 who are at high risk for progression to severe COVID-19 because of age or medical conditions, if taken within 5 days of symptom onset.³
- **Antivirals are underutilized in high-risk populations, including those residing in nursing homes.** ^{4 5}
- **Racial inequities persist in COVID-19 treatment access and providers should ensure equitable access to treatment for all populations.**
- **Nirmatrelvir/ritonavir (Paxlovid) oral and intravenous remdesivir (Veklury) are preferred antiviral drugs.** Molnupiravir (Lageviro) is an alternate agent that may be prescribed if the preferred treatments are not appropriate or accessible. ([NIH COVID-19 Treatment Guidelines](#)).
- **Prevention continues to be critical. Recent COVID-19 vaccination continues to effectively** lower the risk of serious illness and complications.⁶

Oral antivirals have transitioned to the commercial market and several programs have been developed to ensure access to antiviral medications at low or no cost. For more information on the transition, see <https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/COVID19-Tx-Transition-Guide.aspx>

Emergency Use Authorized (EUA) Paxlovid product is being transitioned to commercially packaged new drug application (NDA)-labeled Paxlovid. Any remaining supply of U.S. government-issued EUA Paxlovid product can continue to be dispensed to patients until supplies are depleted or until the [Emergency Use Authorized product expires on March 8, 2024](#).

Treatment locator

The Department of Health and Human Services [COVID-19 Treatments Locator](#) can be used to find availability of COVID-19 antiviral treatment. This will include pharmacies participating in the patient assistance program PAXCESS.

Alto Pharmacy

In New York City, Alto Pharmacy will no longer be providing U.S. government-purchased oral antiviral treatments as part of the New York City Health Department's Home Delivery Program. Alto Pharmacy will stock commercially packaged new drug application (NDA)-labeled nirmatrelvir/ritonavir (Paxlovid) and molnupiravir (Lagevrio) and dispense and deliver them per

routine procedures (e.g., billing insurance with associated co-pays). Alto Pharmacy is participating in the Pfizer patient assistance program for eligible patients (see below).

Home Test to Treat

Home Test to Treat (<https://www.test2treat.org/s/>) also offers free evaluation and treatment for eligible patients for COVID-19 and Influenza, regardless of insurance status.

Clinicians should recommend to patients that they call ahead to their pharmacy to confirm availability of the medication and whether there will be co-payments or other charges.

Patient Assistance Programs

Patient assistance programs have been developed to help ensure uninsured and underinsured patients have continued access to these critical and timely treatments. **Counsel your patients on these programs when prescribing antivirals and help them enroll or provide them with the necessary information to do so to avoid unnecessary costs or delays in treatment.**

Provider resources and patient education materials can be found at:

paxlovid.pfizerpro.com/access-support/access and merckhelps.com/LAGEVRIO.

Providers can obtain co-pay vouchers nirmatrelvir/ritonavir (Paxlovid) through this program to give to patients prescribed this medication.

Currently, most people who have insurance coverage through **Medicare** will need to enroll in Pfizer's patient assistance program (PAXCESS) to access Paxlovid at no cost through 2024. **If they do not enroll, they may have to pay for it out-of-pocket and will not be reimbursed.**

Antiviral Treatment Coverage and Access

Paxlovid (nirmatrelvir/ritonavir) Coverage and Access Programs	
Uninsured/ Medicare/ Tricare/ CHIP (no cost for medication through 2024)	<ul style="list-style-type: none">• Patients must enroll in Pfizer's PAXCESS Patient Assistance Program before picking up their prescription to avoid out-of-pocket costs.• The patient, caregiver, provider, or pharmacist can enroll by visiting https://paxlovid.iassist.com or calling 877-C19-PACK (877-219-7225) to complete a short application.• Prescriptions can only be filled at a PAXCESS participating pharmacy, which can be found at the HHS Treatment Locator (treatments.hhs.gov).• Patients will not be reimbursed for out-of-pocket costs retrospectively if they do not enroll in the PAXCESS program.• Patients also have the option to request overnight mailing of the prescription via FedEx (Sundays excluded) by calling 877-219-7225.

<p>Medicaid (no cost for medication through 2024)</p>	<ul style="list-style-type: none"> • Patients may obtain their prescription directly from Medicare/Medicaid participating pharmacies OR • Prescribers, patients or pharmacies may also choose to use the patient assistance program (PAP) PAXCESS to obtain nirmatrelvir/ritonavir (Paxlovid) for patients at no cost: https://www.paxlovid.com/paxcess
<p>Some Medicare part D plans (no cost for medication through 2024)</p>	<ul style="list-style-type: none"> • Patients may obtain their prescription directly from Medicare/Medicaid participating pharmacies (please check with your Medicare part D plan) OR • Prescribers, patients or pharmacies may also choose to use the patient assistance program (PAP) PAXCESS to obtain nirmatrelvir/ritonavir (Paxlovid) for patients at no cost: https://www.paxlovid.com/paxcess
<p>Commercial insurance (billed through insurance and co-pays apply-PAXCESS assistance for co-pays)</p>	<ul style="list-style-type: none"> • Patients may obtain co-pay assistance via Pfizer’s Co-Pay Savings Program. • Patients can go to paxlovid.com/paxcess or call 877-219-7225 to enroll in the Co-Pay Savings Program prior to picking up the prescription at any pharmacy (not limited to pharmacies enrolled in Pfizer’s PAXCESS program). • Patients who have paid a co-pay for Paxlovid may be eligible for a rebate. Information and forms are available at: paxlovid.com/paxcess.

<p>Lagevrio (molnupiravir) Coverage and Access Programs</p>	
<p>Uninsured/Medicare</p>	<ul style="list-style-type: none"> • A Patient Assistance Program is available for people without health insurance or who cannot afford the medication (income limits apply). Visit merckhelps.com/LAGEVRIO for more information on eligibility. • To enroll patients in the program, a health care provider must call 1-800-727-5400 and tell the program representative that they are making an Urgent Need Request for Lagevrio. The program representative will provide further instructions. • If approved, the medication will be overnight shipped to the patient’s address.
<p>Medicaid (no cost through Sept 2024)</p>	<ul style="list-style-type: none"> • Patients with Medicaid may obtain molnupiravir (Lagevrio) with no patient cost sharing through participating pharmacies. Prior authorization may be needed
<p>Medicare part D plans (no cost through Dec 2024, co-pays may apply)</p>	<ul style="list-style-type: none"> • Patients with Medicaid may obtain molnupiravir (Lagevrio) with possible co-pays through participating pharmacies.

<p>Insured (co-pays may apply)</p>	<ul style="list-style-type: none"> • Patients with commercial insurance plans may obtain molnupiravir (Lagevrio). Patients should check with their pharmacy and health plan about co-payment costs. • If a health plan does not cover Lagevrio or if the co-pay is prohibitive, some insured individuals may still qualify for the Patient Assistance Program if they attest to special circumstances of financial and medical hardship, and their income meets the program criteria. Call 1-800-727-5400 to check eligibility.
---	--

For more information on outpatient treatment options, go to the [CDC's Interim Clinical Considerations for COVID-19 Treatment in Outpatients](#) and the [NIH COVID-19 Treatment Guidelines](#).

Thank you for your help in keeping New Yorkers healthy and safe, and ensuring New Yorkers have access to these potentially life-saving treatments.

For additional questions, please contact BCDC at bcdc@health.ny.gov or 518-473-4439.

1. Hansen K, Makkar SR, Sahner D, et al. Paxlovid (nirmatrelvir/ritonavir) effectiveness against hospitalization and death in N3C: A target trial emulation study. *medRxiv* 2023: 2023.05.26.23290602.
2. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. Feb, 9, 2023. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html2024>).
3. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. 10/10/2023 2024).
4. McGarry BE, Sommers BD, Wilcock AD, Grabowski DC, Barnett ML. Monoclonal Antibody and Oral Antiviral Treatment of SARS-CoV-2 Infection in US Nursing Homes. *JAMA* 2023; **330**(6): 561-3.
5. Wilcock AD, Kissler S, Mehrotra A, et al. Clinical Risk and Outpatient Therapy Utilization for COVID-19 in the Medicare Population. *JAMA Health Forum* 2024; **5**(1): e235044.
6. Link-Gelles R, Ciesla AA, Mak J, et al. Early Estimates of Updated 2023-2024 (Monovalent XBB.1.5) COVID-19 Vaccine Effectiveness Against Symptomatic SARS-CoV-2 Infection Attributable to Co-Circulating Omicron Variants Among Immunocompetent Adults - Increasing Community Access to Testing Program, United States, September 2023-January 2024. *MMWR Morb Mortal Wkly Rep* 2024; **73**(4): 77-83.