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# Maine Health Alert Network (HAN) System

## PUBLIC HEALTH ADVISORY

**To:**  Health Care Providers

**From:**  Dr. Isaac Benowitz, State Epidemiologist

**Subject:**  **COVID-19 Outpatient Treatment Commercialization and Access**

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## COVID-19 Outpatient Treatment: Commercialization and Access

**Summary**

COVID-19 continues to circulate in our communities and continues to cause hospitalizations and deaths. Access to timely testing and outpatient treatment is crucial to reducing severe disease. Two oral antiviral drugs, Paxlovid and Lagevrio, previously freely available, are now commercially available. Most people will still be able to access treatment in a timely manner at pharmacies or health care facilities. Uninsured or underinsured people may face new barriers to treatment access, and new patient assistance programs are now available to support these populations. Providers should become familiar with these changes to COVID-19 antiviral access and insurance coverage to support their patients and help ensure timely care. Facilities offering COVID-19 antiviral drugs to their patients should order from commercial distributors now and should prepare to assist all patients with obtaining COVID-19 treatment via multiple pathways.

**Background**

Paxlovid and Lagevrio, the oral COVID-19 antiviral drugs available in the U.S., have been available for free to all eligible people since the initial authorizations of both drugs in December 2021. Both drugs are now moving to the commercial market. These drugs will continue to be available in pharmacies across the state and in certain healthcare settings. However, the payment model is shifting with implications for access, particularly for people who are uninsured or underinsured and people on public insurance plans. Veklury, an intravenous antiviral drug, also remains available for use in inpatient and outpatient settings.

To be eligible for COVID-19 oral antiviral treatment, a person must have COVID-19 symptoms and a positive test, be within 5 days of symptom onset, and have one or more risk factors for severe disease:
- Age over 50 years, with risk increasing substantially at age ≥65 years
- Being unvaccinated or not being up to date on COVID-19 vaccinations
- Specific medical conditions, including immunocompromising conditions

Some racial and ethnic minority groups are disproportionately affected by COVID-19 because of many factors, including limited access to vaccines and healthcare. Clinicians can consider these factors when evaluating the risk for severe COVID-19 and use of therapeutics.

NIH COVID-19 Treatment Guidelines *Therapeutic Management of Nonhospitalized Adults* recommends **Paxlovid** as the first-line preferred option for treating mild/moderate COVID-19 in outpatient settings. **Veklury** (remdesivir) is the second-line preferred therapy. **Lagevrio** (molnupiravir) is an alternative therapy for use when the preferred therapies are not available, feasible to use, or clinically appropriate.

**Paxlovid (nirmatrelvir-ritonavir)**
- Most patients will continue to be able to obtain Paxlovid by getting a prescription from a provider and filling that prescription at a pharmacy, as they would do for any other prescription medication.
- Medicare, Medicaid (MaineCare), and uninsured patients can get Paxlovid for free through 2024 via Pfizer's U.S. Government Patient Assistance Program (USG PAP). The Patient Assistance Program includes all patients publicly insured through Medicare, Medicaid/CHIP (including MaineCare), TRICARE, and VA Community Care Network. Patients will be able to get prescriptions filled at a pharmacy or via overnight mail order. Patients can self-enroll or can be enrolled by a caregiver, a provider, or a pharmacist. For more, visit https://www.paxlovid.com/paxcess.
- Pfizer is also operating a Paxlovid Co-Pay Savings Program that can reduce out-of-pocket costs for eligible commercially insured patients. For more information, visit paxlovid.com (for patients) and paxlovid.pfizerpro.com (for health care providers).

**Lagevrio (molnupiravir)**
- Most patients will continue to be able to obtain Lagevrio by getting a prescription from a provider and filling that prescription at a pharmacy, as they would do for any other prescription medication.
- The Merck Patient Assistance Program provides Lagevrio free of charge to patients who meet its eligibility criteria and who, without assistance, could not otherwise afford the product. Lagevrio is available through this pathway as an urgent need request. The healthcare provider must call 800-727-5400 and indicate that they are making an *Urgent Need Request*. The representative will provide instructions. The provider must follow the program representative's instructions to make the request. Patients may also check their eligibility on MerckHelps (https://merckhelps.com/LAGEVRIO).

**Key Messages for Patients**
- Stay up to date with COVID-19 vaccine by getting the updated 2023–2024 COVID-19 vaccine.
- **Know Your Risk. Get Tested. Get Treated.** If you are at risk for severe illness, have a plan to get tested and treated. Get COVID-19 rapid tests and use them when you have COVID-19 symptoms. Know where to go to see a health care provider who can evaluate you and recommend treatment.
- You may be asked for your insurance information. Patient assistance programs are available to people who are underinsured, uninsured, or on Medicaid or Medicare to lower their out-of-pocket costs. Call ahead to your healthcare provider and insurer to confirm supply and coverage eligibility.
- **For more information about COVID-19 treatment, visit COVID-19 Treatment in Maine.**

## Recommendations for Clinicians

- Continue to educate all patients at risk for severe illness about the importance of timely treatment.
- Offer COVID-19 treatment to all who are eligible, especially older adults and immunocompromised persons, and including persons who have been vaccinated against COVID-19 or previously infected.
- Become familiar with how patients access and pay for COVID-19 outpatient treatment. Patients who are uninsured or underinsured may need additional support to be able to access timely treatment, and certain patients may face delays in access to treatment. Consider pre-enrolling in Pfizer's Patient Assistance Program at https://www.paxlovid.com/paxcess, and familiarize yourself with Merck's Patient Assistance Program at https://www.merckhelps.com/, in order to reduce delays in access.
- **For more information about COVID-19 treatment, visit COVID-19: Healthcare Providers.**

## Recommendations for Health Care Facilities and Pharmacies

- Obtain commercial supplies of Paxlovid and Lagevrio **now** to support timely access to treatment.
- Ensure the availability of COVID-19 treatment on outpatient and inpatient formularies or ensure the availability of treatment through other pathways. Patients who are admitted to an inpatient facility for a reason other than COVID-19 and test positive for COVID-19 and have mild/moderate illness should be offered treatment during the inpatient stay, just as they would if they were not admitted.
- The U.S. government will continue to supply Paxlovid and Lagevrio to federal entities including HRSA, Indian Health Service, VA, and others until supplies are depleted. Facilities associated with one of these federal entities (e.g., federally-qualified health centers, IHS facilities, and VA facilities) should continue to obtain Paxlovid and Lagevrio through established channels, and should reach out directly to those federal entities for further information about obtaining ongoing medication supplies.
- **For more information on the commercialization of COVID-19 therapeutics, visit the ASPR website at Sunsetting the U.S. Government COVID-19 Therapeutics Distribution Program**.

## Recommendations for Pharmacies

- Pharmacies are encouraged to proactively pre-enroll in Pfizer's USG Patient Assistance Program at https://www.paxlovid.com/paxcess, and to familiarize themselves with Merck's Patient Assistance Program at https://www.merckhelps.com/, in order to minimize delays in patient access to treatment.
- Retail pharmacies that would like to participate in the Pfizer USG Patient Assistance Program should contact the program vendor at pharmacynetworkcontract102101@assistrx.com or 877-219-7225.

## Additional Information

- ASPR: COVID-19 Test-to-Treat Locator
- Sunsetting the U.S. Government COVID-19 Therapeutics Distribution Program (updated 12/20/23)
- Transition of Paxlovid to Commercial Distribution (updated 11/28/23)
- Letter to COVID-19 therapeutics manufacturers, distributors, pharmacies and the health care payer community
- Paxlovid FDA Letter of Authorization (updated 11/01/23)
- FDA FAQ on Paxlovid (updated 11/01/23)
- Lagevrio FDA Letter of Authorization (updated 10/03/23)
- FDA FAQ on Lagevrio (updated 10/03/23)