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Maine Health Alert Network (HAN) System

PUBLIC HEALTH ADVISORY

To: All Health Care
From: Dr. Isaac Benowitz, Maine CDC State Epidemiologist
Subject: **Accessing COVID-19 Treatments for Non-hospitalized Patients**
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Accessing COVID-19 Treatments for Non-hospitalized Patients

I. Summary

This health alert provides important updates regarding COVID-19 therapeutics for non-hospitalized patients, including new information on which patients to prioritize for some or all of these medications. It also includes information on locations in the State where patients can get tested, evaluated, and treated with these medications. The approach outlined in this health advisory is subject to change.

Vaccination remains the best way to prevent COVID-19 infection, hospitalization, and death. However, infections, hospitalizations, and deaths continue to occur in unvaccinated individuals and, to a lesser extent, in vaccinated individuals. Several oral and intravenous medications are now available in Maine to prevent progression of COVID-19 infection to hospitalization and death. However, lack of knowledge among patients, supply shortages of several of these medications, and other considerations such as transportation and insurance remain substantial barriers.

Please see earlier Maine public health advisories, US CDC: Using Therapeutics to Prevent and Treat COVID-19 (January 3, 2022) and Update on COVID-19 Therapeutics (January 7, 2022), for further background information on COVID-19 treatment for non-hospitalized patients.

II. Recommended prioritization for COVID-19 therapeutics

At this time, the U.S. faces a shortage of COVID-19 therapeutics. To assist clinicians with making decisions among the available therapeutic options, and to maximize access to treatment to patients at the highest risk of hospitalization or death, Maine CDC analyzed recent COVID-19 case data by age, vaccination status, immune status, and clinical risk factors to identify groups at the highest risk for hospitalization and death, and considered NIH patient prioritization guidance, discussions with health care partners, and other states' experiences. Based on these findings, the Maine CDC recommends

providers prescribe COVID-19 therapeutics for non-hospitalized patients as shown in Table 1, below:

Table 1. Recommended Prioritization for COVID-19 Therapeutics for Non-hospitalized Patients

Category	Who is included in this category	Prioritize for…
Maine Tier 1	• Unvaccinated* individuals who are 50+ years old *and have 1+ clinical risk factors for severe disease*** • Vaccinated* individuals who are 65+ years old *and have 1+ clinical risk factors for severe disease*** • Moderately/severely immunocompromised individuals**** (unvaccinated or vaccinated*) • Pregnant women (unvaccinated or vaccinated*)	• remdesivir • Paxlovid • monoclonal antibodies (currently, sotrovimab only) • molnupiravir
Maine Tier 2	• Unvaccinated* individuals who are 65+ years old • Vaccinated* individuals who are 75+ years old • Vaccinated* individuals who are 50+ years old *and have 1+ clinical risk factors for severe disease*** • Individuals residing in a congregate living facility (e.g., nursing home, assisted living, shelter, jail, prison) who do not otherwise meet Tier 1 or 2 criteria and meet treatment criteria as per FDA EUA and other prescriber information	• Remdesivir • molnupiravir
Maine Tier 3	• All other patients who meet treatment criteria as per FDA EUA and other prescriber information	• Remdesivir • molnupiravir

***Unvaccinated** refers to an individual who has not received 2 doses of an mRNA vaccine or 1 dose of the J&J vaccine. **Vaccinated** refers to an individual who received 2 doses of an mRNA vaccine or 1 dose of the J&J vaccine. Vaccinated individuals who have not received a vaccine booster dose are likely at higher risk for severe disease than those who are boosted, and healthcare providers may choose to prioritize such patients for treatment.*

***Clinical risk factors for severe disease:** some of the most important Underlying Medical Conditions Associated with High Risk for Severe COVID-19 (US CDC) include cancer, cardiovascular disease, chronic kidney disease, chronic lung disease, diabetes, immunocompromising conditions or receipt of immunosuppressive medications, obesity (BMI ≥30), pregnancy, sickle cell disease.*

****Moderate/severe immunocompromise:** Moderately or Severely Immunocompromised People (US CDC) include people who have been receiving active cancer treatment for tumors or cancers of the blood, received an organ transplant and are taking medicine to suppress the immune system, received a stem cell transplant within the last 2 years or taking medicine to suppress the immune system, moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome), advanced or untreated HIV infection, or active treatment with high-dose corticosteroids or other drugs that suppress the immune response.*

Maine's guidelines differ from recently published NIH recommendations in the following areas:

- **Pregnant women (vaccinated or unvaccinated)** are in **Tier 1** and they should be prioritized for access to all available therapies. *NOTE: do not prescribe molnupiravir for pregnant women if other treatment options are available; refer to the FDA EUA materials for further information.*
- **Vaccinated individuals 65+ years old with clinical risk factors** (NIH Tier 3) are in **Tier 1**.
- **Unvaccinated individuals 50-64 years old with clinical risk factors** (NIH Tier 2) are in **Tier 1**.
- **Unvaccinated individuals 75+ years old without risk factors** (NIH Tier 1) are in **Tier 2**.
- **Unvaccinated individuals age <50 years old with clinical risk factors** (NIH Tier 2) are in **Tier 3**.
- **Individuals residing in a congregate living facility** (*e.g.*, nursing home, assisted living facility, shelter, jail, or prison, groups that are not addressed in NIH guidance) who do not otherwise meet Tier 1 or Tier 2 criteria based on vaccination status, age, and clinical risk factors, are in **Tier 2**.

The State is working closely with COVID-19 Outpatient Assessment and Treatment Sites, pharmacies, and other healthcare partners providing these medications in the State, to monitor use of medications and to identify opportunities to improve uptake, particularly by the highest-risk patients. For updated information on current patient prioritization categories and locations offering these treatments, visit

https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/covid19-treatment.shtml.

III. Selection of the best option for an individual patient

The State of Maine currently recommends remdesivir as the first option for patients with mild to moderate illness. Remdesivir is highly effective in preventing disease progression to hospitalization and death, is FDA-approved for outpatient use in patients 12+ years old and 40+ kg at high risk for illness progression, and it is also available under FDA EUA for patients <12 years old and 3.5–<40 kg. It may be started within 0–7 days after COVID-19 symptom onset. There are no supply shortages at this time. Barriers to outpatient use of remdesivir include access to an outpatient setting offering remdesivir infusion, transportation for three consecutive days of IV infusion, and insurance coverage/deductibles.

Patients who cannot be treated with remdesivir as described above should be offered Paxlovid, sotrovimab, and molnupiravir, in that order. Paxlovid, sotrovimab, and remdesivir offer high (i.e., 85–88%) effectiveness in preventing COVID-19 disease progression to hospitalization and death, and molnupiravir is 30% effective in preventing COVID-19 disease progression to hospitalization and death, compared with placebo. **Paxlovid** can be started within 0–5 days after symptom onset and has several drug-drug interactions that could make it unavailable to some patients; most patients should be able to utilize **sotrovimab**, which can be started within 0–10 days after symptom onset. **Molnupiravir** can be started within 0–5 days after symptom onset and is an option for many patients: it should not be used for pregnant women if other options are available, and it cannot be used in patients under 18 years old.

The State's recommendations for prioritization for COVID-19 therapeutics for non-hospitalized patients are intended to help ensure the availability of Paxlovid and sotrovimab, two highly effective treatment options that are in very limited supply, for those highest-risk patients who cannot be treated with remdesivir. Many other patients could still be offered either remdesivir or molnupiravir.

IV. Availability of medications in hospitals, clinics, and pharmacies

The State of Maine is partnering with healthcare institutions around the State to offer a streamlined, coordinated approach to COVID-19 treatment for non-hospitalized patients:

- **COVID-19 Outpatient Assessment and Treatment Sites** offer COVID-19 testing, assessment, and treatment with one or more of the four medications described above, with an emphasis on providing these services for patients in Tier 1 and Tier 2 (see Table 1, above).
- Paxlovid and molnupiravir will continue to be made available, by prescription, at some Walmart and Hannaford pharmacy locations, although that could change based on new strategies.
- Monoclonal antibody provider sites across the State continue to offer sotrovimab and remdesivir. For the current list of monoclonal antibody therapy providers, see https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/mAb_ME%20Providers.pdf. Remdesivir may also be available in additional facilities that are not yet included in that list.

Health care providers can direct patients with mild/moderate COVID-19 who meet treatment criteria to the nearest COVID-19 Outpatient Assessment and Treatment Site. Health care providers could also test and assess patients in their own healthcare facility and determine the best treatment option based on Maine's tier-based guidelines (see Section II) and offer those treatments in the order described above (see Section III), then contact the nearest COVID-19 Outpatient Assessment and Treatment Site to arrange for treatment, or direct the patient to a pharmacy or monoclonal antibody site, as noted above.

V. Recommendations for Health Care Providers

- Continue to encourage COVID-19 vaccination, including booster vaccination.
- Identify patients with mild or moderate COVID-19 who meet treatment criteria in the outpatient setting, counsel them on the value of treatment in preventing progression to hospitalization and death, offer therapeutic options, and initiate treatment.
- Identify patients who could be treated with these medications if they develop mild or moderate COVID-19 illness and help them to make a plan for how to quickly access treatment, such as identifying how to get tested (including obtaining home test kit supplies) and assessed quickly.

VI. Additional information for Health Care Providers

Maine CDC will hold a weekly webinar Fridays at 7:30am, with updates on COVID-19 therapeutics, *starting on February 18, 2022*. These calls will continue weekly through February and March and may then be spaced more widely. The call series is open to all health care providers in the State of Maine.

COVID-19 Vaccines & Therapies (Maine CDC Clinician Info Sessions)
Fridays at 7:30am (beginning February 18, 2022)
https://mainestate.zoom.us/j/83384535429
Meeting ID: 833 8453 5429
One tap mobile
+13017158592,,83384535429# US (Washington DC)
+13126266799,,83384535429# US (Chicago)

For More Information

- COVID-19 Treatment in Maine
- NIH Treatment Guidelines
- NIH Statement on Therapies for High-Risk, Non-hospitalized Patients
- Remdesivir prescribing information
- Remdesivir information (Gilead)
- Remdesivir EUA Fact Sheet for Healthcare Providers
- Remdesivir EUA Fact Sheet for Parents and Caregivers
- Sotrovimab EUA Fact Sheet for Healthcare Providers
- Sotrovimab EUA Fact Sheet for Patients
- Paxlovid EUA Fact Sheet for Providers
- Paxlovid EUA Fact Sheet for Patients
- Molnupiravir EUA Fact Sheet for Providers
- Molnupiravir Fact Sheet for Patients
- Omicron Variant: What You Need to Know | CDC
- COVID-19 Treatment Guidelines: What's New
- COVID-19 Treatment Guidelines: Antiviral Therapy