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PUBLIC HEALTH ADVISORY

To:	All Health Care
From:	Dr. Isaac Benowitz, State Epidemiologist
Subject:	**Increasing Access to COVID-19 Therapies for Non-Hospitalized Patients**
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Increasing Access to COVID-19 Therapies for Non-Hospitalized Patients

I. Summary

COVID-19 transmission continues to occur in Maine. In recent weeks, new cases have dropped under 1,000 cases/day and, in recent days, under 500 cases/day. This is a sharp drop from the recent surge of Omicron-variant infections in Maine in January and February, yet it does not mean we are in the clear. Over 30 COVID-19 deaths were reported to Maine CDC in the first half of March. The daily census of hospitalized COVID-19 patients, over 400 through much of January, just recently dipped below 100. Recent reports from European countries and elsewhere suggest the BA.2 subvariant is likely to cause a resurgence in cases, hospitalizations, and deaths in coming weeks. Many hospitalizations and deaths could be averted through early access to COVID-19 testing and COVID-19 outpatient treatment.

Oral and IV medications are highly effective at preventing progression from mild to severe disease in patients with COVID-19 at high risk for hospitalization or death. Medications are available at several pharmacies, hospitals, and clinics for patients who have mild illness. All treatments require a positive PCR or antigen test result for SARS-CoV-2 and a prescription. **Unfortunately, many patients do not learn about these COVID-19 outpatient therapy options, are unaware of the importance of early treatment for preventing progression to severe disease, or are unable to access early treatment.**

Currently, all available medications are in very good supply in the state and should be offered to all patients eligible for outpatient treatment of COVID-19. Healthcare providers should increase their familiarity with treatment options and how patients access them and educate high-risk patients on the importance of, and access to, COVID-19 treatments. Healthcare providers should offer treatment to high-risk patients when they present for evaluation. Information for the public is available at https://www.maine.gov/covid19/treatment. Further information for healthcare providers is available at https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/covid19-treatment.shtml.

II. Upcoming Webinar: Preventing COVID-19 Severe Disease in Maine

Please join Maine CDC on **Tuesday, March 29, 2022, at 12pm**, for a healthcare provider education session on COVID-19 and how to help prevent infection and severe disease in high-risk patients. Dr. Isaac Benowitz, State Epidemiologist at Maine CDC, will describe recent COVID-19 trends in Maine focusing on severe disease, hospitalization, and death, and cover currently available vaccines and other prevention strategies, along with the latest information on where patients can access treatments in the State. CME is available for physicians through MMA and MOA. There will be time for your questions.

Preventing COVID-19 Severe Disease in Maine — Tuesday, March 29, 2022, at 12pm
Register here: https://mainestate.zoom.us/webinar/register/WN_Ew4lNcE9Q7GPaS7Su8Nj6A

Learning objectives:
1. Describe who is at highest risk for COVID-19-associated hospitalization and death if infected
2. Describe several oral and IV therapeutics for treatment of COVID-19 in the outpatient setting
3. Describe who to treat for COVID-19 and how patients access these treatments in the State

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Maine Medical Education Trust and the Maine CDC. The Maine Medical Education Trust is accredited by the Maine Medical Association Committee on Continuing Medical Education and Accreditation to provide continuing medical education for physicians. The Maine Medical Education Trust designates this live activity for a maximum of 1.0 AMA PRA Category 1™ Credit(s).

The Maine Osteopathic Association is accredited by the American Osteopathic Association to provide osteopathic continuing medical education for physicians. The Maine Osteopathic Association designates this program for a maximum of 1.0 AOA Category 2-A credits and will report CME and specialty credits commensurate with the extent of the physician's participation in this activity.

III. Prevention of COVID-19 Infection

Vaccination remains the primary strategy for prevention of COVID-19 illness, hospitalization, and death. COVID-19 vaccination is recommended for everyone ages 5 years and older in the United States for the prevention of COVID-19. Persons with moderate to severe immunocompromise should get an additional vaccine dose, and are eligible to receive pre-exposure prophylaxis, now widely available.

US CDC's current vaccine recommendations are available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html. Recent changes include a consideration for an 8-week interval between the first and second doses of a primary mRNA vaccine schedule for many individuals who have not yet received the primary series. Vaccine for children age 6 months through 4 years is anticipated to become available in coming weeks but is not yet available in the US.

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19. Because the immune response following COVID-19 vaccination may differ in moderately or severely immunocompromised people, specific guidance for this population is provided; mRNA vaccines are preferred. These individuals are also eligible to receive EVUSHELD for pre-exposure prophylaxis: information on locations in the State offering EVUSHELD is at https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/prophylaxis.shtml. **The recommended dose for EVUSHELD increased in February 2022; any patients who received EVUSHELD before March 2022 should return to receive an additional dose for full effectiveness.**

IV. COVID-19 Treatment in the Outpatient Setting

There are five medications for the treatment of COVID-19 in non-hospitalized patients: two oral antiviral medications, two IV monoclonal antibody medications, and one IV antiviral medication:

Medication	Paxlovid	sotrovimab	remdesivir	bebtelovimab	molnupiravir
Effectiveness	88%	85%	87%	Similar to sotrovimab	30%
Age/eligibility	≥ 12 years	≥ 12 years	Any age*	≥ 12 years	≥ 18 years
Initiate within # days of symptom onset	0–5 days	0–7 days *(was 0–10 days)*	0–7 days	0–7 days	0–5 days
Route of administration	Oral	Intravenous	Intravenous	Intravenous	Oral
Duration of treatment	5 days	1 day	3 days	1 day	5 days
Pros	• High efficacy • Oral	• High efficacy • Single IV infusion	• High efficacy • Greater experience	• High efficacy • Single IV infusion	• Oral • No drug-drug interaction concerns
Cons	• Ritonavir-related drug-drug interactions	• Requires IV infusion	• Requires 3 days of IV infusion	• Requires IV infusion	• Low efficacy • Not authorized for age 0-17 yrs • Avoid in pregnancy • Mutagenicity concerns

**Remdesivir is approved for age 12+ years and available under FDA EUA for patients <12 years old weighing 3.5–40 kg*

The oral antiviral therapies, Paxlovid and molnupiravir, fill the "strategic niche" for outpatient treatment similar to the niche filled by oseltamivir for influenza: these drugs are prescribed within 5 days after symptom onset, possibly without an in-person visit; consider molnupiravir for patients who only have access to oral drugs and have renal impairment, hepatic failure, or certain drug-drug interactions preventing the use of Paxlovid. *The supply of these drugs has increased in the past month and is expected to remain stable in coming weeks. In the mid- to long term, these medications are expected to be the most available of the current options for outpatient treatment.*

The IV monoclonal antibody therapies, sotrovimab and bebtelovimab, can be used within 7 days after symptom onset. Access is limited based on the need for an infusion site. *Future COVID-19 variants could be resistant to these therapies.*

IV remdesivir has seen increased outpatient use, building on extensive experience in inpatient settings. It is given as a series of three IV infusions over three days. Supply is excellent. Remdesivir is covered by insurance. Transportation, logistics, and insurance are real barriers. A patient assistance program is available to defray patient costs: https://www.gilead.com/purpose/medication-access/us-patient-access

In general, patients should be offered Paxlovid first, then sotrovimab, remdesivir, bebtelovimab, and then molnupiravir last, only if no other options are accessible/available. Some providers have expressed concerns with use of antivirals in pregnant patients, preferring to offer the monoclonals first.

V. COVID-19 Treatments in Maine

Paxlovid, sotrovimab, bebtelovimab, and molnupiravir are available in Maine and no shortages have been reported recently; supply is very good for all of these and all these medications should be offered to patients eligible for treatment per FDA Emergency Use Authorization criteria. Additionally, remdesivir continues to be available at selected hospital locations in the State.

Maine CDC has made the following information available to the public and for healthcare providers. These web pages will be updated to include additional communications resources and further updates.

- **For patients:** *COVID-19 Treatment in Maine* (https://www.maine.gov/covid19/treatment) provides information on who should get treated and when and treatment types. The page lists the hospital, clinic, and pharmacy locations in the State where patients can access treatment. All sites are open to the public. Some sites offer telehealth services and can ship certain medications to some patients.

- **For providers:** *COVID-19 Treatment for Non-Hospitalized Patients (Information for Providers)* (https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/covid19-treatment.shtml) provides information on currently-available treatments, current recommendations for prioritization during scarcity, and information on current supplies of medications in the State.

VI. Increasing Uptake of COVID-19 Outpatient Treatment

The outpatient therapies described above can drastically reduce the risk of severe disease in a person with mild to moderate COVID-19 disease and have been available in Maine for several months. And yet we continue to see hospitalizations and deaths. There is a need to increase awareness among the general public that these medications are available and have a profound impact on disease progression.

Key messages for healthcare providers:

- Become familiar with COVID-19 treatments for outpatients
- Talk to your high-risk patients about the value of treatment
- Encourage high-risk patients to have a plan to get tested and treated before they get sick

Key messages for high-risk patients:

- COVID-19 treatments are safe and effective and drastically reduce the risk of severe disease
- Treatment must be started within the first few days after symptom onset to be effective
- Have a plan to get tested, evaluated, and treated if you develop symptoms of COVID-19

VI. Recommendations for Healthcare Providers

- Continue to encourage COVID-19 vaccination, including booster vaccination, in everyone 5+.
- Encourage high-risk patients to get vaccinated and get a booster. Immunocompromised patients should receive an additional vaccine dose and are eligible to receive pre-exposure prophylaxis.
- **Communicate with your high-risk patients that treatment for COVID-19 is available in Maine and needs to be started soon after symptom onset. Encourage high-risk patients to have a plan to get promptly tested, evaluated, and treated if they get sick.**
- Obtain further information on clinical use of products through NIH's COVID-19 Treatment Guidelines, the Assistant Secretary for Preparedness and Response Public Health Emergency COVID-19 Therapeutics site, and through professional societies such as IDSA's Guidelines on the Management of Patients with COVID-19.

For More Information

- Maine CDC: COVID-19 Treatment in Maine (Information for Providers)
- Maine CDC: COVID-19 Treatment for Non-Hospitalized Patients (Information for Providers)
- Maine CDC: COVID-19 Pre-Exposure Prophylaxis (Information for Providers)
- ASPR: COVID-19 Therapeutics
- NIH: COVID-19 Treatment Guidelines: What's New
- NIH: COVID-19 Treatment Guidelines: Antiviral Therapy
- NIH: Statement on Therapies for High-Risk, Nonhospitalized Patients

Join Maine CDC's monthly clinician call for updates on vaccines and therapies:

COVID-19 Vaccines & Therapies (Maine CDC Clinician Info Sessions)
Second Tuesday of the month at 12pm (April 12, May 10, June 14, July 12, etc.)
Click to connect: **https://mainestate.zoom.us/j/83384535429**
Meeting ID: 833 8453 5429
One tap mobile: +13017158592,,83384535429# US (Washington DC)
One tap mobile: +13126266799,,83384535429# US (Chicago)