Department of Health and Human Services
Maine Center for Disease Control and Prevention
286 Water Street
11 State House Station
Augusta, Maine 04333-0011
Tel: (207) 287-8016; Fax (207) 287-9058
TTY Users: Dial 711 (Maine Relay)

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PUBLIC HEALTH ADVISORY

To: All HAN Recipients
From: Dr. Isaac Benowitz, State Epidemiologist
Subject: **Deauthorization of Bebtelovimab Treatment for COVID-19**
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Deauthorization of Bebtelovimab Treatment for COVID-19

FDA today revoked the emergency use authorization for bebtelovimab, a monoclonal antibody therapy. **Accordingly, bebtelovimab may no longer be used for COVID-19 treatment in the U.S.** With the continued appearance of new variants, COVID-19 infection is now likely to be due to variants resistant to all monoclonal antibody therapies. Healthcare facilities offering COVID-19 monoclonal antibody treatment should explore offering Veklury to patients who cannot receive Paxlovid and should retain outpatient infusion capacity for COVID-19 monoclonal antibody therapies that could be authorized later.

Clinicians should refer to NIH COVID-19 Treatment Guidelines for up-to-date recommendations related to eligibility, effectiveness, sub-populations, drug classes, and therapeutic management, including therapeutic management of non-hospitalized children. COVID-19 testing remains a crucial link to treatment, since treatment is only available to people with COVID-19 symptoms and a positive antigen or PCR test for SARS-CoV-2 infection who have one or more risk factors for severe COVID-19, including age over 50 years (with risk increasing substantially at age ≥65 years), being unvaccinated or not being up to date on COVID-19 vaccinations, and specific medical conditions and behaviors.

NIH continues to recommend Paxlovid (ritonavir/nirmatrelvir) as first-line therapy for outpatient treatment, and Veklury (remdesivir) as second-line therapy. Lagevrio (molnupiravir) is an alternative therapy for patients who cannot get either Paxlovid or Veklury. Paxlovid decreases hospitalization: a recent report found that among U.S. adults with COVID-19, including those with previous infection or vaccination, persons prescribed Paxlovid within 5 days of diagnosis had a 51% lower hospitalization rate than those not prescribed Paxlovid. COVID-19 rebound, a recurrence of symptoms after initial improvement, is not linked to any specific drug, and concerns about rebound are not a good reason to avoid treatment. Paxlovid's drug-drug interactions can often be addressed by using interaction checkers or consulting with a pharmacist. Maine CDC has developed COVID-19 treatment provider resources, including pre-recorded case-based training videos.

COVID-19 continues to cause substantial morbidity and mortality in the U.S. despite successes with vaccination and treatment. It remains the third leading cause of death after heart disease and cancer. The largest proportion of COVID-19 deaths is in adults 65+ years old (especially 85+ years old) and people with certain underlying medical conditions or disabilities. Most deaths in adults 18–49 years old were in unvaccinated persons. Racial and ethnic disparities in COVID-19–related mortality have decreased; however, gaps persist. COVID-19 vaccines reduce the risk of dying in all groups, including older adults; ≥2 booster doses give the most protection. COVID-19 vaccines are recommended for people age 6 months and older; bivalent vaccine products are recommended for people age 5 years and older. People who are immunocompromised should be offered pre-exposure prophylaxis with Evusheld, if eligible.