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PUBLIC HEALTH ADVISORY

To: Health Care Providers

From: Dr. Isaac Benowitz, State Epidemiologist

Subject: **Evusheld No Longer Authorized for Emergency Use in the U.S.**

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Evusheld (tixagevimab/cilgavimab), a long-acting antibody for prevention of COVID-19, is no longer authorized for use due to a lack of effectiveness against currently circulating COVID-19 variants. Similar products are under development but are not yet available in the US. COVID-19 vaccines remain effective against COVID-19 infection and severe disease, and several antiviral treatments continue to be excellent treatment options for COVID-19.

For the latest information about COVID-19 vaccines and therapies, visit Maine CDC's COVID-19: Vaccines and Therapeutics (Provider Information) page. New information about long-acting antibody treatments will be posted to Maine CDC's COVID-19 Pre-Exposure Prophylaxis: Information for Providers page when it becomes available.

Evusheld No Longer Authorized for Emergency Use in the U.S.

The U.S. Food and Drug Administration (FDA) announced on January 26, 2023, that the Emergency Use Authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab) has been revised and based on this revision, Evusheld is not currently authorized for use in the U.S. This is because it is unlikely to be active against more than 90% of the SARS-CoV-2 variants currently circulating in the U.S. based on the latest CDC data. However, people who have used Evusheld still have options to increase their protection against the most serious consequences of COVID-19, including hospitalization and death.

According to the most recent CDC Nowcast data, certain SARS-CoV-2 variants are projected to make up more than 90% of the variants currently circulating in the U.S. This means that Evusheld is not expected to provide protection against developing COVID-19 if exposed to those variants. Given that a COVID-19 infection is likely to be caused by one of these non-susceptible variants, and consistent with the terms and conditions of the Letter of Authorization, Evusheld is not currently authorized for emergency use in any U.S. region at this time. HHS and AstraZeneca have paused distribution of Evusheld until further notice by the Agency.

People who are immunocompromised, older adults, and people with disabilities continue to face increased risks from COVID-19. HHS has ramped up efforts to get high-risk populations vaccinated—and ensure their timely access to tests and lifesaving treatments. Through these efforts, Paxlovid and Lagevrio are now widely available at pharmacies, Test to Treat sites, long-term care facilities, and other sites; and states have been encouraged to set up infusion clinics for Veklury.

More details about these and other treatment options that are expected to retain activity against COVID-19 can be found here and below:

- Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

- Lagevrio is authorized for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

- Veklury is approved for the treatment of adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

- COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in inpatient or outpatient settings.

Individuals for whom COVID-19 vaccination is recommended should consider getting vaccinated with the primary series and an updated vaccine when eligible to increase protection against the most serious consequences of COVID-19.

For additional information about Evusheld, please visit the FDA's website and view ASPR's information page.