Delaware Health Update #493: Removal of Emergency Use Authorization of bebtelovimab

The Delaware Division of Public Health (DPH), Office of Emergency Services and Hospital Preparedness is issuing updated guidance on the administration of bebtelovimab.

Summary

On November 30, 2022, The U.S. Food and Drug Administration (FDA) announced that bebtelobimab is not currently authorized for emergency use in the U.S. because it is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1.

Data from the Centers for Disease Control and Prevention (CDC) estimates that the combined proportion of COVID-19 cases caused by the Omicron BQ.1 and BQ.1.1 subvariants to be above 57% nationally with a sustained trend of increasing prevalence across all regions. Given that a COVID-19 infection is likely to be caused by a non-susceptible SARS-CoV-2 variant, and consistent with the terms and conditions of the Letter of Authorization, **bebtelovimab is not currently authorized for emergency use in any U.S region at this time.**

The U.S. Government recommends all product be retained in the event that SARS-CoV-2 variants susceptible to bebtelovimab, which are currently circulating at lower prevalence, become more prevalent in the future in the United States. Retained product must be appropriately held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for bebtelovimab.

Recommendations

Health care providers should use other approved or authorized products that are expected to retain activity against BQ.1 and BQ.1.1 as they choose appropriate treatment options for patients, which include the following:

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.

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.

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.

In addition**, 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 or, if vaccinated with the primary series, boosted with an updated bivalent vaccine when eligible to increase protection against the most serious consequences of COVID-19, including hospitalization and death.

All treatment sites can continue ordering Paxlovid, Veklury, and Lagevrio by following the existing ordering processes and reporting procedures, as applicable.
FDA will continue to work with ASPR, the CDC, and the National Institutes of Health on surveillance of variants that may impact the use of the therapies authorized for emergency use.

How to obtain therapeutics:

Veklury is now a commercial product and can be ordered from the following sites:

Gilead Pharmaceuticals: https://www.gilead.com/remdesivir
remdesivir@amerisourcebergen.com

Paxlovid and Lagevrio, Evusheld can be ordered through the Office of Emergency Medical Services. Send an inquiry to OEMS@delaware.gov. You will receive a call for directions for onboarding and ordering therapeutics.

Resources

https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-bebtelovimab-not-currently-authorized-any-us-region

https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Bebtelovimab

https://www.covid19treatmentguidelines.nih.gov