FDA Announces Bebtelovimab is Not Currently Authorized in Any US Region

[11/30/2022] The U.S. Food and Drug Administration today announced bebtelovimab 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., according to data included in the Health Care Provider Fact Sheet (/media/156152/download).

Nowcast data (https://covid.cdc.gov/covid-data-tracker/#variant-proportions) from the Centers for Disease Control and Prevention published last week 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, and already above 50% in all individual regions but one, and data shows 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**.

Eli Lilly and its authorized distributors have paused commercial distribution of bebtelovimab until further notice by the Agency. Additionally, the Administration for Strategic Preparedness and Response (ASPR) has paused the fulfillment of any pending requests under its Bebtelovimab Product Replacement Initiative (https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Bebtelovimab/Pages/default.aspx).

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 (/media/156152/download) and the Letter of Authorization for bebtelovimab (/media/156151/download).

Health care providers should use other approved or authorized products (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) 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 (/media/155050/download) 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 (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214787Orig1s010Lbl.pdf)

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 (/media/155054/download) 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 (/media/141478/download) 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.

For more information related to the therapeutic management of non-hospitalized patients with mild-to-moderate COVID-19, refer to the NIH COVID-19 Treatment Guidelines (https://www.covid19treatmentguidelines.nih.gov/management/clinical-management-of-adults/nonhospitalized-adults--therapeutic-management/).

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. We will provide further updates and consider additional action as new information becomes available.