Omicron Subvariants Predominance Leads to EVUSHELD Halt

There are currently no COVID-19 monoclonal antibodies authorized for any use

Background

The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for a number of investigational neutralizing antibody therapies during the COVID-19 pandemic, including:

- 11/09/20 – **Eli Lilly's bamlanivimab monotherapy [*EUA not currently authorized*]**
- 11/21/20 – **Regeneron's combination REGEN-COV: casirivimab + imdevimab [*EUA not currently authorized*]**
- 02/09/21 – **Eli Lilly's combination bamlanivimab + etesevimab [*EUA not currently authorized*]**
- 05/26/21 – **GSK's sotrovimab monotherapy [*EUA not currently authorized*]**
- 12/08/21 – **AZ's PrEP combination EVUSHELD: tixagevimab + cilgavimab [*EUA not currently authorized*]**
- 02/11/22 – **Eli Lilly's bebtelovimab monotherapy [*EUA not currently authorized*]**

Issue

On 01/26/23, the FDA has updated the EUA for EVUSHELD and rescinded the authorization for use as pre-exposure prophylaxis of COVID-19 in every U.S. region as it is not expected to neutralize the Omicron BQ.1, BQ.1.1, BF.7, BF.11, BA.5.2.6, BA.4.6, BA.2.75.2, XBB, and XBB.1.5 subvariants. Distribution of these products has also been halted at this time.

Nowcast data from the Centers for Disease Control and Prevention estimates that the combined proportion of COVID-19 cases caused by the non-susceptible Omicron subvariants to be above 90% nationally.

What Healthcare Providers Should Do

Healthcare providers should discontinue use of EVUSHELD as it is not currently authorized for use in any U.S. region and as such, providers are not afforded PREP Act protections.

Similar to previous halts, the U.S. Department of Health and Human Services acknowledges that COVID-19 countermeasure efficacy remains dynamic as variant frequency changes. Accordingly, the FDA may re-authorize COVID-19 monoclonal antibodies for specific geographic regions in the future if variant prevalence shifts. Please refer to the FDA Emergency Use Authorization website for the most up to date Fact Sheets.

Paxlovid, Veklury, and Lagevrio are expected to retain activity against these Omicron subvariants.

PharMerica Continues to Provide Support

While COVID-19 monoclonal antibodies are not currently authorized for any use nor are being distributed, PharMerica continues to pledge support in facilitating access to currently authorized therapies, including Veklury™ and the oral countermeasures.

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