Omicron Predominance Leads to Bamlanivimab/Etesevimab and REGEN-COV Halt

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 revoked*]**
- 11/21/20 – **Regeneron's combination REGEN-COV: casirivimab + imdevimab [*Distribution halted 1/25/2022*]**
- 02/09/21 – **Eli Lilly's combination bamlanivimab + etesevimab [*Distribution halted 1/25/2022*]**
- 05/26/21 – **GSK's sotrovimab monotherapy**

Issue

On 01/25/22, the FDA has updated the EUAs for bamlanivimab/etesevimab and REGEN-COV and revoked the authorization for use as treatment or post-exposure prophylaxis of COVID-19 in every U.S. region. Allocation and distribution of these products has also been halted at this time.

The Omicron variant has been shown to exhibit an unacceptably high rate of resistance to these neutralizing antibodies. The CDC released data that confirms that Omicron is circulating at a prevalence of greater than 97.8% in all regions and nationally greater than 99%.

What Healthcare Providers Should Do

Healthcare providers should discontinue use of bamlanivimab/etesevimab and REGEN-COV as they are 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 bamlanivimab/etesevimab and REGEN-COV 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.

Treatments that do work against Omicron will continue to be distributed by States through their individual processes. Sotrovimab, Evusheld, Paxlovid and molnupiravir are included in federal allocations.

PharMerica Continues to Provide Support

While bamlanivimab/etesevimab and REGEN-COV therapies are not currently authorized and distributed, PharMerica continues to pledge support in facilitating access to currently authorized therapies, including sotrovimab and the oral countermeasures.

Please reference PharMerica's updated Coronavirus Monoclonal Antibodies Policy & Procedures for details on ordering, preparing, administering, monitoring and other essential details for the provision of these EUA-authorized therapies. If needed, please contact your Account Manager for a copy of this Policy and Procedures.

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