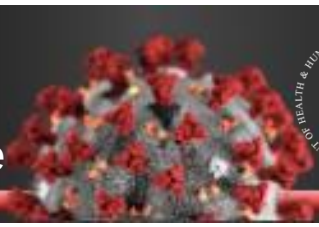
Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update



May 24, 2021

Suspected COVID-19 P.1 Variant Resistance to bamlanivimab/etesevimab

The Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services are committed to ensuring timely and transparent communication regarding the monoclonal antibody therapies currently authorized for emergency use in certain patients for the treatment of COVID-19.

The Centers for Disease Control and Prevention (CDC) has identified that the P.1 variant (originally identified in Brazil) is circulating with a frequency exceeding 10% in Massachusetts **(https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html)**. Results from in vitro assays that are used to assess the susceptibility of viral variants to particular monoclonal antibodies suggest that bamlanivimab and etesevimab administered together are not active against the P.1 variant. These assays use "pseudo-virus particles" that help determine likely susceptibility of the live virus.

REGEN-COV (casirivimab and imdevimab) is an alternative monoclonal antibody therapy that is currently authorized for the same use as bamlanivimab and etesevimab administered together and, based on similar in vitro assay data currently available, REGEN-COV is likely to retain activity against the P.1 variant. All treatment delivery sites can continue ordering REGEN-COV from the authorized distributer by following the existing ordering and reporting procedures. The FDA recommends that health care providers in Massachusetts use this alternative authorized monoclonal antibody therapy until further notice. ASPR will pause distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under **EUA 094**) to Massachusetts. As per the **prior communication (May 7, 2021)**, the P.1 variant has been persistently elevated at a frequency exceeding 20% in Illinois, and the shipping restriction to Illinois remains in effect.

Other states, including those neighboring Massachusetts, are not impacted by today's announcement. All health care providers should monitor information from the CDC and state and local health authorities regarding the frequency of the P.1 variant in their region.

Health care providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody therapy available under an **EUA** for details regarding specific variants and resistance. Health care providers should also refer to the CDC website and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

Monoclonal antibody therapies available under an EUA must be used in accordance with the terms and conditions for the respective authorization, including the authorized labeling. ASPR and FDA will continue to work with the CDC and the National Institutes of Health on surveillance of variants that may impact the use of the monoclonal antibody therapies authorized for emergency use. We will provide further updates and consider additional action as new information becomes available. Providers are welcome to contact **COVID19Therapeutics@hhs.gov** with any questions.

References:
1. U.S. Department of Health and Human Services. Office of the Assistant Secretary of Preparedness and Response. Bamlanivimab/etesevimab; May 21, 2021: Important Update. Accessed May 24, 2021.