



June 29, 2021

Pause in Distribution and Utilization of Bamlanivimab/Etesevimab

On June 25, 2021, the HHS Assistant Secretary for Preparedness and Response (ASPR) announced an immediate pause involving distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with an existing supply of bamlanivimab) on a national basis until further notice. ***In addition, the FDA recommends that health care providers nationwide use alternative authorized monoclonal antibody therapies (REGEN-COV and Sotrovimab), as described below, and to avoid use of bamlanivimab and etesevimab administered together for the management of COVID-19 at this time.***¹

The Centers for Disease Control and Prevention has identified that the combined frequencies of the SARS-CoV-2 P.1/Gamma variant (first identified in Brazil) and the B.1.351/Beta variant (first identified in South Africa) throughout the United States now exceed 11% and are trending upward (<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html>).² Results from in-vitro assays used to assess the susceptibility of viral variants to particular monoclonal antibodies suggest that bamlanivimab and etesevimab administered together are not active against either the P.1 or B.1.351 variants. Lack of bamlanivimab/etesevimab activity against the COVID-19 P.1 variant has been [suspected and reported earlier](#).³

[REGEN-COV](#) and [sotrovimab](#) are alternative monoclonal antibody therapies that are currently authorized for the same use as bamlanivimab and etesevimab administered together. Based on similar in-vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1 or B.1.351 variants. Regarding the availability of the two alternatives above;

- I/T/U sites can continue ordering REGEN-COV through the IHS National Supply Service Center by following the existing ordering procedures (i.e., Form 413).
- The IHS National Supply Service Center (NSSC) is presently engaged with the manufacturer of sotrovimab regarding procurement for I/T/U sites. It is expected that this agent will become available for request, at no cost, from NSSC shortly.

Clinicians should review the Antiviral Resistance information in Section 15 of the Healthcare Provider Fact Sheets for each monoclonal antibody therapy available under an [EUA](#) for details related to specific variants and resistance. Health care providers should also refer to the [CDC Variant Proportions webpage](#) and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

References:

1. Department of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. Public Health Emergency. [Pause in the distribution of bamlanivimab/etesevimab](#). Published June 25, 2021.
2. Centers for Disease Control and Prevention. [COVID Data Tracker: Variant Proportions](#). Assessed June 28, 2021.
3. Indian Health Service. National Pharmacy and Therapeutics Committee. [COVID-19 Emerging Treatment Update: Suspected COVID-19 P.1. Variant Resistance to bamlanivimab/etesevimab](#). Published May 24, 2021.