Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update

December 23, 2021

Updated FDA Guidance- Monoclonal Antibodies & Omicron Variant
Pause in Distribution of Certain MABs

On December 23, 2021, the HHS Assistant Secretary for Preparedness and Response (ASPR) announced a pause involving distribution of bamlanivimab and etesevimab together, etesevimab alone (to pair with an existing supply of bamlanivimab), and REGEN-COV on a national basis pending updated data from the Centers for Disease Control and Prevention (CDC) regarding the SARS-CoV-2 Omicron variant.[1] In addition, the FDA recommends that health care providers nationwide consider use of the alternative authorized monoclonal antibody therapy, sotrovimab, as described below, in regions with a higher frequency of Omicron.

Circulating SARS-CoV-2 viral variants, including Omicron, may be associated with resistance to monoclonal antibodies. The CDC publishes information about circulating variants in the United States by region. The CDC has identified that the frequency of the SARS-CoV-2 B.1.1.529//Omicron variant (first identified in South Africa) throughout the United States now exceeds 73% and is trending upward (www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html).[2] **Health care providers should refer to this frequency data as they choose the best therapeutic option for their patients.**

FDA updated the Health Care Provider Fact Sheets for bamlanivimab and etesevimab administered together, REGEN-COV, and sotrovimab with specific information regarding expected activity against the Omicron variant (B.1.1.529). These data show that it is unlikely that bamlanivimab and etesevimab administered together or REGEN-COV will retain activity against this variant.

Sotrovimab is a monoclonal antibody therapy that is currently 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. **Based on cell culture data currently available, sotrovimab appears to retain activity against the Omicron variant.**

Regarding the availability of Monoclonal Abs for COVID-19;

- The IHS National Supply Service Center is presently receiving allocations of sotrovimab from the U.S. Government.
- I/T/U sites can continue ordering bamlanivimab/etesevimab together, etesevimab alone, REGEN-COV, and sotrovimab through the IHS National Supply Service Center by following the existing ordering procedures (i.e., Form 413).

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. ASPR pauses allocation of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV. Published Dec 23, 2021.
2. Centers for Disease Control and Prevention. COVID Data Tracker: Variant Proportions. Assessed Dec 23, 2021.