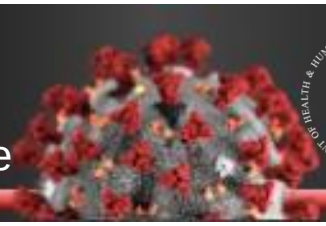
Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update



April 6, 2022

Distribution of Sotrovimab Paused to all U.S. States and Territories

On April 5, 2022, the Centers for Disease Control and Prevention (CDC) estimated the proportion of COVID-19 cases caused by the Omicron BA.2 variant to be above 50% in all U.S. Department of Health and Human Services (HHS) regions. Due to these data, use of sotrovimab is not authorized in any U.S. state or territory at this time. **Accordingly, and effective immediately, the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) has paused sotrovimab distribution to all U.S. states and territories.**

The FDA has updated the Fact Sheet for sotrovimab to reflect product use restrictions. The FDA statement can also be found here.

The FDA recommends that health care providers in all U.S. states and territories use alternative authorized therapy until further notice. Currently authorized alternative treatments are available for distribution. These include, Paxlovid® (an oral antiviral treatment) and molnupiravir (an alternative oral antiviral for patients for which Paxlovid is not appropriate or accessible). Additionally, bebtelovimab is an alternative monoclonal antibody therapy that is currently authorized and available for distribution. Based on similar in vitro assay data currently available, these products are likely to retain activity against the BA.2 variant. All treatment delivery sites can continue ordering Paxlovid®, molnupiravir (Lagevrio), and bebtelovimab from the authorized distributer by following the existing ordering and reporting procedures.

Health care providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody and oral antiviral therapy available under an EUA for details regarding specific variants and resistance. Health care providers should also refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html) and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

References:

1. U.S. Health & Humans Services. Office of the Assistant Secretary for Preparedness and Response. Important Update: Distribution of Sotrovimab Paused to all U.S. States and Territories. Published April 5, 2022.
2. U.S. Food and Drug Administration. FDA updated sotrovimab emergency use authorization. Published April 5, 2022.
3. U.S. Food and Drug Administration. Sotrovimab. FACT SHEET FOR HEALTHCARE PROVIDERS. Updated March 25, 2022.
4. Indian Health Service. National Pharmacy and Therapeutics Committee. COVID-19 Clinical Guidance: Paxlovid.
5. Indian Health Service. National Pharmacy and Therapeutics Committee. COVID-19 Clinical Guidance: Molnupiravir
6. Indian Health Service. National Pharmacy and Therapeutics Committee. COVID-19 Clinical Guidance: Bebtelovimab