



March 28, 2022

Distribution of Sotrovimab Paused to Certain States

On March 25, 2022, the Centers for Disease Control and Prevention (CDC) identified that the BA.2 variant is now circulating with a frequency exceeding 50% in Health and Human Services (HHS) Region 1 (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont) and Region 2 (New Jersey, New York, Puerto Rico, and the Virgin Islands) <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 sotrovimab is not fully active against the BA.2 variant. The FDA [Fact Sheet](#) for sotrovimab was updated on March 25, 2022 to reflect new data using authentic live BA.2 virus.

Accordingly, ***the Office of the Assistant Secretary for Preparedness & Response (ASPR) will immediately pause distribution of sotrovimab to all states in Region 1 (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont) and Region 2 (New Jersey, New York, Puerto Rico, and the Virgin Islands)***. Other states, except those noted above, 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 BA.2 variant in their region.

Currently authorized alternative COVID-19 outpatient 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, each of these products are likely to retain activity against the BA.2 variant. All treatment delivery sites can continue ordering Paxlovid, bebtelovimab and molnupiravir from the authorized distributor by following the existing ordering and reporting procedures. The FDA recommends that health care providers in all states in Regions 1 and 2 use alternative authorized therapy until further notice.

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 & Response. [Important Update: Distribution of Sotrovimab Paused to Certain States](#). Published March 25, 2022.
2. U.S. Food and Drug Administration. Emergency Use Authorization for Sotrovimab. [FACT SHEET FOR HEALTHCARE PROVIDERS](#). Updated March 25, 2022.
3. Indian Health Service. National Pharmacy and Therapeutics Committee. [COVID-19 Clinical Guidance: Paxlovid](#).
4. Indian Health Service. National Pharmacy and Therapeutics Committee. [COVID-19 Clinical Guidance: Molnupiravir](#).
5. Indian Health Service. National Pharmacy and Therapeutics Committee. [COVID-19 Clinical Guidance: Bebtelovimab](#).