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Provider Alert

New York State Department of Health Issues Advisory: Sotrovimab No Longer Authorized to Treat COVID-19 in Any U.S. Region – Pause in Distribution

The New York State Department of Health (NYSDOH) issued an Advisory on March 25, 2022, announcing a pause in the distribution of sotrovimab.

Please review the updated FDA fact sheet for sotrovimab prior to prescribing: **fda.gov/media/149534/download**.

For current NYSDOH information on monoclonal antibodies, please refer to **COVID-19 Monoclonal Antibody (mAb) Therapeutics Information for Providers**.

As of April 5, 2022, sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 variant.

The **Centers for Disease Control and Prevention (CDC) Nowcast data** from April 5, 2022, estimate that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all Health and Human Services (HHS) U.S. regions. Data included in the **healthcare provider fact sheet** show that the authorized dose of sotrovimab is unlikely to be effective against the BA.2 variant. Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time.

Healthcare providers should use **other approved or authorized products** as they choose appropriate treatment options for patients. The FDA will continue to monitor BA.2 in all U.S. regions and will provide follow-up communication when appropriate.

Currently authorized alternative treatments are available for distribution. These include Paxlovid (an oral antiviral treatment) and molnupiravir (an alternative oral antiviral for patients for whom 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, bebtelovimab, and molnupiravir from the authorized distributor by following the existing ordering and reporting procedures.

Healthcare 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. Healthcare providers should also refer to the CDC website (**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.

COVID-19 therapies available under an EUA must be used in accordance with the terms and conditions for the respective authorization, including the authorized labeling. The Letters of Authorization may be accessed at **fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs**.