NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Date: March 25, 2022
To: Health Care Providers and Health Care Facilities
From: New York State Department of Health

Pause in distribution of Sotrovimab

The New York State Department of Health received notification today regarding the following message:

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

The Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services are committed to ensuring timely and transparent communication regarding the COVID-19 monoclonal antibody treatments that are currently authorized for emergency use in certain patients for the treatment of COVID-19.

The Centers for Disease Control and Prevention (CDC) has identified that the BA.2 variant is now circulating with a frequency exceeding 50% in 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, 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 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, bebtelovimab and molnupiravir from the authorized distributer 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.

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: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

ASPR and FDA will continue to work with the CDC and the National Institutes of Health on surveillance of variants that may impact the use of the therapies authorized for emergency use. We will provide further updates and consider additional action as new information becomes available.