LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-13: FDA Restricts Use of Monoclonal Antibody Sotrovimab to Treat COVID-19 Due to the Omicron BA.2 Variant**
Origination Date: *April 6, 2022*	**Revision Dates (List All Revision Dates):**

FDA Restricts Use of Monoclonal Antibody Sotrovimab to Treat COVID-19 Due to the Omicron BA.2 Variant

On Tuesday, April 5, 2022 the U.S. Food and Drug Administration (FDA) restricted the use of the monoclonal antibody sotrovimab nationwide. The FDA states that because data show sotrovimab is highly unlikely to be active against the Omicron BA.2 lineage, which now accounts for a majority of new COVID-19 cases in all regions of the country, **sotrovimab is no longer authorized to treat COVID-19. Accordingly, shipments of sotrovimab from the federal government will cease until further notice.**

As of April 5, 2022, U.S. Centers for Disease Control and Prevention (CDC) Nowcast data estimates BA.2 accounts for 72% of all new cases nationally and 67% of new cases in U.S. Health and Human Services (HHS) Region 6, which includes Louisiana.

Full HHS message will be pasted below.

Monoclonal antibody providers that have remaining sotrovimab doses on hand are asked to maintain their stock in appropriate storage, if able, in the event it may be of use in the future.

The oral therapeutics Paxlovid (nirmatrelvir/ritonavir) and Lagevrio (molnupiravir) as well as the monoclonal antibody bebtelovimab are likely to retain activity against the BA.2 variant and remain available. Patients and clinicians can access the HHS Therapeutics Locator to find available supply: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

HHS Message

Dear Stakeholders,

Today, 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, 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 be found here.*

Currently authorized alternative treatments are available for distribution. These include, Paxlovid (an oral antiviral treatment) and Lagevrio (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, Lagevrio, and bebtelovimab from the authorized distributer by following the existing ordering and reporting procedures. The FDA recommends that health care providers in all U.S. states and territories 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.

Please contact COVID19Therapeutics@hhs.gov with any questions.

Thank you,
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