Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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Distribution of Sotrovimab Paused to All HHS Regions

On April 5, 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 percent in all U.S. Department of Health and Human Services (HHS) regions. Because of these data, use of Sotrovimab monoclonal antibody treatment for COVID-19 is not authorized in any U.S. state or territory at this time.

Effective immediately, the Office of the Assistant Secretary for Preparedness & Response (ASPR) has paused Sotrovimab distribution to all U.S. states and territories. The Food & Drug Administration (FDA) has updated the Fact Sheet for Sotrovimab to reflect product use restrictions.

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).

Bebtelovimab remains 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.

The dosage of bebtelovimab in adults (18 years and older) and pediatric patients (≥12 years of age and weighing at least 40 kg) is 175 mg. The drug must be administered as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 7 days of symptom onset. Bebtelovimab must be administered as a single intravenous injection over at least 30 seconds.

Patients receiving the treatment must be clinically observed for at least 1 hour after injection is complete for possible infusion-related reactions. Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of other SARS-CoV-2 monoclonal antibodies and could occur with administration of bebtelovimab.

All treatment delivery sites can continue ordering Paxlovid, Lagevrio, and Bebtelovimab from the authorized distributor 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 Emergency Use Authorization (EUA) for details regarding specific variants and resistance.

Additional Resources and Information

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

Fact Sheet for Patients, Parents, and Caregivers: http://pi.lilly.com/eua/bebtelovimab-eua-factsheet-patient.pdf

Fact Sheet for HealthCare Providers: http://pi.lilly.com/eua/bebtelovimab-eua-factsheet-hcp.pdf

Federal Locator for Therapeutics
https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

Alabama Locator for Therapeutics
https://alpublichealth.maps.arcgis.com/apps/MapSeries/index.html?appid=d84846411471404c83313bfe7ab2a367