8/27/2021

MEMORANDUM

TO: Monoclonal Antibody Therapy Provider Sites in Illinois
Hospital and Infusion Site Administrators
Hospital and Infusion site Pharmacists
Regional Hospital Coordinating Centers
Local Health Departments

FROM: Ashley Thoele, MSN, MBA, RN
Division Chief, EMS and Highway Safety
Office of Preparedness and Response

RE: **Update to bamlanivimab and etesivimab administration under the EUA**

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 currently authorized for emergency use in certain patients with COVID-19.

Today, we are informing you of changes in the authorized use of bamlanivimab and etesevimab administered together under Emergency Use Authorization (EUA) 094. Specifically, the EUA now authorizes the use of bamlanivimab and etesevimab, administered together, only in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%. Bamlanivimab and etesevimab, administered together, will **not** be authorized for use in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together exceeds 5%.

Based on the above, bamlanivimab and etesevimab administered together are currently authorized for use in the states of Colorado, Connecticut, **Illinois**, Indiana, Iowa, Kansas, Maine, Massachusetts, New Hampshire, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Ohio, Rhode Island, South Dakota, Utah, Vermont, Wisconsin, and Wyoming, which comprise HHS regions 1, 5, 7, and 8. Effective today, ASPR will resume distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under EUA 094) to these states.

FDA has posted a list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab administered together are currently authorized, and a list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab, administered together, are not currently authorized and will periodically update both lists as new data and information becomes available. FDA will make this determination considering current variant frequency data, trends in variant frequency over time, and the precision of the estimates and information regarding emerging variants of concern.

The Centers for Disease Control and Prevention (CDC) determined that the frequency of the SARS-CoV-2 B.1.617.2/Delta variant (first identified in India) is increasing throughout the U.S. and has become the dominant variant in the US. Based on in vitro assays that are used to assess the susceptibility of viral variants to monoclonal antibodies, bamlanivimab and etesevimab, administered together, **are** expected to retain activity against the Delta variant (B.1.617.2). Based on these in vitro assays, bamlanivimab and etesevimab, administered together, **are not** expected to retain activity against the SARS-CoV-2 P.1/Gamma variant (first identified in Brazil), the B.1.351/Beta variant (first identified in South Africa), the AY.1 and AY.2 variants/Delta[+K417N] (commonly known as "Delta plus," first identified in India) and the B.1.621 variant (first identified in Colombia). With the emergence of the B.1.617.2/Delta variant as the dominant variant in the U.S., the frequency of identified variants expected to be resistant to bamlanivimab and etesevimab administered together is steadily decreasing.

Supplies of bamlanivimab and etesevimab that are already in distribution in a state, territory, or U.S. jurisdiction in which the product is not currently authorized may remain in distribution and be held for future use if the combined frequency of variants resistant to bamlanivimab and etesevimab administered together in that state, territory, or U.S. jurisdiction become less than or equal to 5%. Health care providers should refer to the Fact Sheet for Health Care Providers for appropriate storage conditions.

At present, three monoclonal antibody therapies - bamlanivimab and etesevimab administered together, REGEN-COV, and sotrovimab - are authorized for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. REGEN-COV and sotrovimab may be used, consistent with the terms and conditions of their respective authorizations, in all states, territories, and U.S. jurisdictions including those in which bamlanivimab and etesevimab are not currently authorized. Based on similar in vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1, B.1.351, AY.1 and AY.2, B.1.621, and B.1.617.2/Delta variants. As such, the use and distribution of REGEN-COV and sotrovimab are not impacted by the circulating variants based on information available at this time. All treatment delivery sites can continue ordering REGEN-COV from the authorized distributer by following the existing ordering and reporting

procedures. All treatment sites may also find information on the availability and ordering of sotrovimab by visiting GlaxoSmithKline's website.

Health care providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody therapy available under an EUA for details regarding specific variants and resistance. Health care providers should also refer to the CDC website, and information from state and local health authorities regarding reports of viral variants of importance in their region.

Monoclonal antibody 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 Emergency Use Authorization: Drug and Biological Therapeutic Products page.

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 monoclonal antibody therapies authorized for emergency use. We will provide further updates and consider additional action as new information becomes available.

Additional contacts:
IDPH technical assistance contact for monoclonal antibody therapy ashley.thoele@illinois.gov.
Therapeutic Questions: Please contact COVID19Therapeutics@hhs.gov.
AmeriSource Bergen: C19therapies@amerisourcebergen.com
REGEN-COV Direct Ordering Process link
Sotrovimab Direct Ordering Process via GlaxoSmithKline's website

Are you registered in SIREN?

SIREN is the state's Health Alert Network that provides tools and capacity for rapid, reliable, and secure web-based alerting. SIREN is the emergency planning, alerting, and notification system for IDPH.

Please use this link to guide you to the correct registration instructions for your public health related classification: http://www.dph.illinois.gov/siren