6/25/2021

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: **UPDATES:** Monoclonal Antibody Therapeutics – **IMMEDIATE PAUSE OF DISTRIBUTION** of bamlanivimab and etesevimab

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 that ASPR is immediately pausing all distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under EUA 094) on a national basis until further notice. In addition, FDA recommends that health care providers nationwide use alternative authorized monoclonal antibody therapies, as described below, and not use bamlanivimab and etesevimab administered together at this time.

The Centers for Disease Control and Prevention (CDC) has identified that the combined frequencies of the SARS-CoV-2 P.1/Gamma variant (first identified in Brazil) and the B.1.351/Beta variant (first identified in South Africa) throughout the United States now exceed 11% and are trending upward (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 bamlanivimab and etesevimab administered together are not active against either the P.1 or B.1.351 variants. These assays use “pseudotyped virus-like particles” that help determine likely susceptibility of the live SARS-CoV-2 variant viruses.

REGEN-COV and sotrovimab are alternative monoclonal antibody therapies that are currently authorized for the same use as bamlanivimab and etesevimab administered together. Based on similar in vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1 or B.1.351 variants. 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 at www.sotrovimab.com.

Healthcare 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 (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.

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

Additional resources:

IDPH Contact for monoclonal antibody therapy contact ashley.thoele@illinois.gov.

Therapeutic Questions: Please contact COVID19Therapeutics@hhs.gov.

Direct Ordering Process contacts AmeriSource Bergen: C19therapies@amerisourcebergen.com

We thank you for your continued support and efforts in the fight against COVID-19.