5/7/2021

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: **IMPORTANT UPDATE:** Monoclonal Antibody Therapeutic ASPR/FDA **Update May 7, 2021**

The Office of 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 all stakeholders receive timely and transparent communication regarding COVID-19 monoclonal antibody treatments currently authorized for emergency use in certain patients for the treatment of COVID-19.

As of May 4, 2021, Centers for Disease Control and Prevention have identified that the P.1 variant (originally identified in Brazil) is circulating with increasing prevalence in the state of Illinois (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html). Data from pseudotyped virus-like particle assays suggests that bamlanivimab and etesevimab are not active against the P.1 variant. Other authorized monoclonal antibody therapies remain available and are expected to retain activity against this variant. **The FDA recommends that health care providers in the State of Illinois use alternative authorized monoclonal antibody therapies until further notice. ASPR will pause distribution of the bamlanivimab and etesevimab product as well as etesevimab alone to Illinois.**

All health care providers should monitor information from the CDC and state and local health authorities regarding the frequency of the P.1 variant in their region.

REGEN-COV is an alternative monoclonal antibody therapy that is currently authorized for the same use as bamlanivimab and etesevimab and, based on scientific information currently available, the REGEN-COV product is likely to retain activity against the P.1 variant. All treatment delivery sites can continue ordering REGEN-COV from the authorized distributer by following the existing ordering and reporting procedures.

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 Centers for Disease Control and Prevention (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.

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.

Project Speed: Any healthcare partners interested in becoming a SPEED partner can contact covidtx@hhs.gov.

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

Weekly webinars:
Learn about clinical models and the administration models at the COVID-19 Outpatient Therapeutics Mini Series