3/26/2021

MEMORANDUM

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

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

RE: Monoclonal Antibody Therapeutic Updates

Monoclonal antibody therapy is an option for those diagnosed with COVID-19 and meet high-risk criteria for severe illness but do not require hospitalization. In addition to the allocations to hospitals and infusion sites of care, the U.S. Department of Health and Human Service's (HHS) Special Projects for Equitable and Efficient Distribution (SPEED) program is focused on increasing availability of outpatient therapeutics to vulnerable and underserved populations. This project includes partners such as long-term care facilities, dialysis centers, federally qualified health centers (FQHCs), and correctional facilities and Project SPEED assists these sites is assessing their readiness to receive and administer monoclonal antibody therapy.

IDPH receives weekly distribution and utilization reports from HHS and can monitor the utilization for the available therapies based on the information reported by infusion sites. Utilization by Illinois infusion sites has decreased over the previous two months. IDPH continues to encourage the use of monoclonal antibody therapy for those who meet high risk criteria as a potential mechanism to prevent severe COVID-19 illness and/or hospitalization. Hospitals are encouraged to develop mechanisms to provide monoclonal antibody infusion therapy or partner with infusion sites for referrals of COVID-19 positive patients who meet high-risk criteria.

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 remain committed to ensuring you receive timely and transparent communication regarding the COVID-19 monoclonal antibody treatments that are currently authorized for emergency use in certain patients for the treatment of COVID-19.

Given the sustained increase in SARS-CoV-2 viral variants in the United States that are resistant to bamlanivimab administered alone, and the availability of other authorized monoclonal antibody therapies that are expected to retain activity to these variants, the U.S. Government, in coordination with Eli Lilly and Company, has stopped the distribution of bamlanivimab alone as of March 24, 2021.

FDA recently updated the authorized Fact Sheet for Healthcare Providers for the bamlanivimab emergency use authorization (EUA). This update advised healthcare providers to consider the use of alternative authorized monoclonal antibody therapies that are expected to retain activity against circulating viral variants. Using an alternative authorized monoclonal antibody therapy may reduce the risk of treatment failure should a patient be infected with a SARS-CoV-2 viral variant that is resistant to bamlanivimab alone. Alternative monoclonal antibody therapies that are currently authorized for the same use include bamlanivimab and etesevimab administered together and REGEN-COV.

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.

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. Our federal partners will provide further updates and consider additional action as new information becomes available.

Monoclonal Antibody Ordering

All treatment delivery sites will continue to be able to order bamlanivimab and etesevimab, to be administered together, or REGEN-COV from the authorized distributer following existing ordering and reporting procedures. Additionally, sites can order etesevimab alone to pair with the current supply of bamlanivimab the site has available. Monoclonal antibody therapies available under an EUA must be used in accordance with the terms and conditions for the respective authorization. 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.

Sites can manually order from AmeriSource Bergen using this link: https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8

All sites will be limited to 48 patient courses per site per week, though sites with higher utilization can request additional courses.

Distributive Resources

All healthcare providers in the community should distribute monoclonal antibody therapy information to their patients upon evaluation and testing for COVID-19. Local testing sites should distribute flyers to those seeking testing and encourage follow up with trusted healthcare providers if they test positive and for further guidance and to evaluate if they meet criteria for monoclonal antibody therapy.

IDPH is in the process of updating the distributive resources on the website to include bamlanivimab/etesevimab and when available, can be found here.

Additional resources can be found on the Combat COVID HHS website here. An example flyer that can be used for distribution is linked here.

Healthcare providers can find the closest available monoclonal antibody therapy infusion site via the treatment locator link provided by the National Infusion Center Association and HHS Protect.

Reporting via Teletracking on COVID-19 Therapeutics

Distribution to individual sites is dependent on mandatory therapeutics reporting. Additional reporting fields were added this week in Teletracking for the new therapeutic combinations. Any sites that have previously received etesevimab/bamlanivimab, should report any historical utilization this week in Teletracking. For bamlanivimab/etesevimab report all quantities on hand and utilized week to date when reporting for the first time.

Accuracy and timely reporting by infusion sites is critical to monitoring distribution and utilization and the direction of future monoclonal antibody therapy allocations.

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