4/17/2021

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: Monoclonal Antibody Therapeutic ASPR **Update April 16, 2021**

The Office of the Assistant Secretary for Preparedness and Response (ASPR) remains committed to ensuring healthcare partners receive timely and transparent communication regarding monoclonal antibody treatments currently authorized for emergency use in certain patients for the treatment of COVID-19.

On April 16, 2021, the U.S. Food and Drug Administration (FDA) revoked the emergency use authorization (EUA) for bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients who are at high risk of disease progression or hospitalization.

Please see the full FDA statement here.

REGEN-COV as well as bamlanivimab and etesevimab (administered together) continue to be available under EUA. There is no shortage of monoclonal antibody product. Sites that are administering monoclonal antibodies can order bamlanivimab and etesevimab, etesevimab to pair with the current supply of bamlanivimab that the site has available, or REGEN-COV from the authorized distributer using the direct ordering process.

ASPR will continue to work with Federal partners on monoclonal antibody therapies authorized for emergency use and will provide updates as they become 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 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