KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES

TEAM KENTUCKY

Kentucky Public Health
Prevent. Promote. Protect.

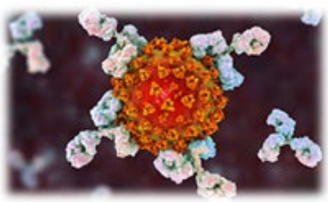
Monoclonal Antibody (mAb) Therapeutics Program
Information for Clinicians and Healthcare Entities

Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus, are intended to prevent progression of the disease, and are most effective when given early in infection. Since Nov 9th, 2020, Kentucky hospitals and clinicians have administered mAbs for the treatment of recently diagnosed, mild to moderate COVID-19 illness in high-risk patients who are not hospitalized. mAb administration has been expanded and successfully implemented in a variety of outpatient settings. KDPH encourages hospitals, clinics and other healthcare entities to coordinate to increase access to mAbs with the goal of reducing hospitalizations.

Current guidance

Recent updates allow for administration of mAbs via subcutaneous injection and for post-exposure prophylaxis.

For current information and clinical guidance, please refer to the HHS Federal Response to COVID-19: Monoclonal Antibody Playbook – updated July, 30, 2021 and manufacturers guidance.



- **Regen-COV:**
  https://www.regencov.com/
  https://www.covid19.lilly.com/assets/pdf/bam-ete/lilly-antibodies-playbook.pdf
- **Bamlanivimab / Etesevimab:**
  https://www.covid19.lilly.com/bam-ete/hcp
  https://www.covid19.lilly.com/assets/pdf/bam-ete/lilly-antibodies-playbook.pdf

The Federal Allocation and Ordering Process

- KDPH is no longer involved in the allocation process but HHS/ASPR continues to manage the distribution of mAb products under EUA as stated in the FDA Letters of Authorization.
  https://www.phe.gov/emergency/events/COVID19/healthcare-facilities/Pages/default.aspx#step3
- All sites that meet the requirements for administering monoclonal antibody therapeutics must order bamlanivimab/etesevimab (Lilly), and/or REGEN-COV (Regeneron) directly from AmerisourceBergen Corporation (ABC), the drugs' sole distributor. The products remain free of charge to requesting sites. To learn more, see the direct ordering process guide and place orders directly with ABC using the C19 Therapies Direct Order Request system.
- For questions regarding the direct order process please email COVID19Therapeutics@hhs.gov
- No clinical data reporting is required beyond established mechanisms for tracking and reporting serious adverse events. Data reporting of utilization is required through TeleTracking or KDPH for acute-care hospitals.

If you have additional questions about mAbs, the ordering process and/or sharing best practices please contact:

Kenneth Kik, KDPH Preparedness Branch at: Kenneth.kik@ky.gov

Additional mAbs Links

https://www.phe.gov/emergency/events/COVID19/Pages/default.aspx

HHS Protect Public Data Hub — Therapeutics Distribution Location

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

8/30/2021