Important Updates Regarding the Direct Order and Reporting Process for Monoclonal Antibodies

August 3, 2021

The federal government is responsible for the allocation and distribution of monoclonal antibody (mAb) therapeutics for the treatment of COVID-19 pursuant to the Emergency Use Authorizations (EUAs) issued by the United States Food and Drug Administration (FDA). The federal government has developed a process for practitioners and facilities to order directly from the distributor, AmerisourceBergen (ABC). These details and resources are listed below. Facilities that may request resources may include hospitals, skilled nursing facilities, and long-term care facilities.

Process Overview

- Facilities (based on classes of trade), are able to order bamlanivimab/etesevimab (Lilly), etesevimab (Lilly – to pair with bamlanivimab already on hand) and/or REGEN-COV (Regeneron) monoclonal antibodies for their facilities.
- Facilities will be required to:
    - Provide ABC with a board of pharmacy license or physician letter of authorization.
    - Attest to their designated class of trade and that they will administer the authorized product according to the terms of the FDA issued EUAs.
    - Provide utilization data via either TeleTracking or Centers for the Disease Control and Prevention's National Healthcare Safety Network (NHSN).
- Facilities can order product based on established minimum amounts; subsequent orders are subject to a maximum amount based on previous orders and utilization.

Required Utilization Reporting

- Weekly reporting on these therapeutics is required every Wednesday through the United States Department of Health and Human Services (HHS) Protect, TeleTracking, or NHSN depending on facility type.
- Instructions are included at the bottom of the ABC order form and included here for reference.
    - To improve availability of treatments for Monoclonal Antibody (mAb) therapies for COVID-19 patients across the nation, the federal government requires entities receiving shipments of mAb treatments to provide weekly reports of mAb treatments administered and stocks on hand through one of the following reporting mechanisms:
        - **For Hospitals**, mAb therapeutic data reporting is included in the COVID-19 hospital data reporting as described in HHS FAQ/Guidance.

    - **Skilled Nursing Facilities / Long Term Care Facilities** are requested to provide data through the NHSN data system at a future date (guidance forthcoming).

    - **All Additional Facilities** such as Dialysis Centers, Home Health Services, Oncology, and Infusion Centers, are required to provide the requested data through the United States Health Care COVID-19 Portal.

- First-time users will receive enrollment and reporting instructions in an e-mail from protect-noreply@hhs.gov with the subject line of "Invitation: HHS TeleTracking COVID-19 Portal." This email provides step-by-step instructions to access the portal for the first time. If you do not receive an email in the next 48 hours, please contact TeleTracking's Technical Support at hhs-protect@teletracking.com.

Health care providers decide whether these investigational treatments are appropriate to treat COVID-19. Find facilities administering this treatment by using the National Infusion Center Locator.

Additional Resources

- Monoclonal Antibody Resources for Clinicians
- Monoclonal Antibody COVID-19 Infusion
- Bamlanivimab and Etesevimab EUA Letter of Authorization February 25 2021
- Regeneron EUA Letter of Authorization July 30, 2021