Overview of Direct Order Process for COVID-19 Therapeutics

Purpose:

The United States Government (USG) is responsible for the allocation and distribution of monoclonal antibody (mAb) therapeutics for the treatment of COVID-19 as per the Emergency Use Authorizations (EUA) issued by the U.S. Food and Drug Administration (FDA). The USG has developed a process for sites to directly order from the distributor, AmerisourceBergen (ABC).

Process overview:

- Sites **(based on classes of trade), are able to order bamlanivimab (Lilly) and/or casirivimab/imdevimab (Regeneron) monoclonal antibodies for their facilities at the link listed below**
- **Sites 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 EUA**
  - **Provide utilization data via either TeleTracking or NHSN**
- Sites can order product based on established minimum amounts; subsequent orders are subject to a maximum amount based on previous orders and utilization
- State departments of health will be informed of therapies ordered within their jurisdictions for awareness.

Link to order: https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8

Required utilization reporting:

- Weekly reporting on these therapeutics is ***required every Wednesday*** through HHS Protect, TeleTracking, or CDC's National Healthcare Safety Network (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 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 US Dept. of Health and Human Services FAQ/Guidance on linked here: https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf
    - Skilled Nursing Facilities / Long Term Care Facilities are requested to provide data through the CDC's 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 following portal: https://teletracking.protect.hhs.gov/
- 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