COVID-19 Monoclonal Antibody (mAb) Checklist: Subcutaneous and Intravenous Administration

TEAM ROLES/RESPONSIBILITIES

Leadership responsibilities

- Ensure ordering process is implemented
- Ensure required elements for administration are available
  - Personnel
  - Supplies
  - Administrative support
  - Identified site for administration
- Determination of scheduling process/logistics if treatment and PEP provided at the same site (as not all patients are COVID-positive)
- Determine mechanism for reimbursement of administration fees (product provided by the US Government is provided at no cost)
- Consider mechanism for interpreter services if patients are non-English speaking

Administrative responsibilities

- Receiving Product: Effective, September 13, 2021, the U.S. Department of Health and Human Services transitioned from a direct ordering process for COVID-19 monoclonal antibody therapeutics (mAbs) to a state/territory-coordinated distribution system. Please request product from your state or territory’s health department.
- Utilization reporting through Teletracking. See https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx

Clinical Responsibilities

- If MD/NP/PA is on site, they can provide order for mAb after patient intake/screening completed
- Patient intake (healthcare provider type determined by state regulations/ scope of practice)
  - Ensure patient is masked for duration of encounter
  - Patient registration completed
  - Vital signs obtained (ensure patient does not require oxygen unless on home 02, therefore making them ineligible for mAb therapy and requiring escalation of care)
- Eligibility criteria reviewed
  - Treatment eligibility criteria
  - Post exposure Prophylaxis Criteria
- Patient Fact Sheet provided to patient prior to administration of mAb
  - Patient Fact Sheet (English) - https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf
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- “Discharge” patient after one hour post-administration monitoring if stable and without symptoms of severe adverse reaction
- Report any severe adverse events as required by the FDA through the process outlined in the EUA

REQUIRED SUPPLIES

Infrastructure

- Seating area for patients to receive mAb, and area for post-administration monitoring (patients could receive and be monitored in the same seat, or be moved to a monitoring area). Spacing should allow for distancing between patients particularly when in a mobile model.
- Steel table for product preparation
- Privacy screens if needed
- Protocol/outline for patient flow *(formal protocol not required, however flow and infection control should be addressed at each administration site)*
- Emergency response plan *(written protocol not required, however site staff should be aware of plan for emergency response)*

Administrative

- Site-specific documentation
- Patient fact sheets to provide each patient (copies in English and Spanish)

Patient Intake

- Vital Signs Machine
- Pulse oximeter
- Thermometer
- Copies of eligibility checklist for treatment/PEP

Administration

- Refrigerator/cooler for storage of mAb product at 2°C to 8°C (36°F to 46°F)
- General Supplies
  - Sharps container
  - Biohazard bags if intravenous infusion utilized
  - Trash bags
  - Trash bins if a fixed site
  - Disposable disinfecting wipes
  - Hand sanitizer
  - Paper towels
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Administration (continued)

- **PPE**
  - NIOSH-approved, disposable fit tested N95 filtering facepiece respirators or higher-level respirators
  - Gloves in all sizes
  - Gowns
  - Surgical masks for patients
  - Eye protection for staff

- **Administration supplies- subcutaneous**
  - Alcohol wipes
  - 3 or 5 mL luer lock syringes (4 required for each patient receiving subcutaneous administration)
  - Appropriate needles for product preparation and subcutaneous administration
    - 21 gauge 1.5 inch needles for product transfer
    - 25 or 27 gauge needles for subcutaneous administration (4 per each patient course)

- **Administration supplies- intravenous**
  - IV poles
  - Alcohol wipes
  - 2x2 gauze
  - Adhesive bandages
  - Medical tape
  - Absorbent underpads
  - Normal saline bags for mixing/administration- 50 to 250ml bag size. Per EUA, bag size will determine infusion time
  - IV administration set- polyvinyl chloride (PVC) infusion set with/without DEHP containing 0.2 or 0.22 micron polyethersulfone (PES) in-line filter
  - Dial-a-flow (IV gravity flow rate regulator)- *IV pumps are not required*
  - IV catheters
  - IV extension set tubing
  - IV dressings
  - Saline flush syringes
  - Appropriately sized syringes
  - Needles appropriate for withdrawing mAb product for mixing (21 gauge 1.5 inch needles)
  - Transilluminator (vein finder)- optional

- Should be available at all sites
  - Epinephrine (e.g., prefilled syringe or autoinjector)- at least 3 doses
  - H1 antihistamine (e.g., diphenhydramine, cetirizine)
  - Blood pressure monitor
  - Timing device to assess pulse
- If feasible, include at sites (not required)
  - Oxygen
  - Bronchodilator (e.g., albuterol)
  - H2 antihistamine (e.g., famotidine, cimetidine)
  - Intravenous fluids
  - Intubation kit with ambu bag
  - CPR pocket mask

Examples of staff plans (recommended positions may vary depending on the state scope of practice for paramedics as it related to subcutaneous and or intravenous administration of medications or mAbs. Medical assistants may also be utilized in states where practice allows subcutaneous administration of medications)

**8-10 bed mAb infusion/observation site**
- 1 physician / advanced practitioner (present or available via telemedicine)
- 2 Nurses
- 1 Nurse or Paramedic
- 2 Paramedics
- 1 flex position – administrative/ logistics/ runner

**Single station or mobile visit Subcutaneous administration site**
- 1 physician / advanced practitioner (present or available via telemedicine)
- 1 Nurse / Paramedic per single mobile visit or single station

Average patient (door to door) visit can range from 80-120 minutes.