Monoclonal Antibody Administration

I. Authorization for Administration

A. Intravenous administration, per MCA selection

MCA Selection for IV Infusion
☐ Paramedic
☐ EMT-Specialist

B. Subcutaneous administration, per MCA selection

MCA Selection for Subcutaneous Administration
☐ Paramedic
☐ EMT-Specialist
☐ EMT- Basic

C. EMS personnel who have been trained and authorized to administer mAb by the subcutaneous (SC) route may be permitted to administer mAb by SC route.
   i. Training must include supervised practice in both drawing up and administering the medication using aseptic technique.
   ii. This must include direct supervision/observation in delivering at least 6 subcutaneous injections of medication to actual patients. Supervision can be provided by clinicians with experience providing mAb therapies (RN, EMT-P).
   iii. Personnel must be authorized by medical control prior to administering medication.

II. Verify that the patient meets current criteria[1]. Current criteria are available on the medication-specific Fact Sheet for Health Care Providers and allows for clinical judgement. Trained and authorized EMS personnel may administer monoclonal antibodies with a patient specific order from a physician or other authorized prescriber or is operating under a physician standing order.

III. Monoclonal Antibody Administration

A. Assure that the standardized order form (or other comparable approved order form) is complete and signed (electronic okay) by the ordering prescriber and that the form matches the medication being administered. A verbal order, signed by a licensed healthcare professional or EMS personnel, is acceptable.

[1] Criteria may change. This protocol is applicable to the criteria in the most current FDA published Fact Sheets for Health Care Providers for the specific mAb medication used.

B. Provide a copy of the Fact Sheet for Patients, Parents, and Caregivers appropriate to the medication to be used and that the patient or the patient's authorized representative has signed a copy of Fact Sheet and agrees to have the medication administered.
    i. The signed Fact Sheet should become part of the EMS patient care record and a copy provided to the ordering prescriber.
    ii. If the patient is unable to sign, the ordering prescriber or the facility is responsible for assuring the authorized representative has received the Fact Sheet and agrees to treatment.
    iii. Fact Sheet for Patients, Parents and Caregivers are located here.
C. Refer to the appropriate Fact Sheet for Healthcare Provider for detailed information on the specific medication being administered. This document should be accessible at all times and should be reviewed prior to the authorized EMS personnel administering this medication for dosing and administration specifics. All authorized mAb medications may administered by the intravenous route for treatment of mild to moderate COVID-19. The use of mAb for post exposure prophylaxis and use by the subcutaneous (SC) route have been authorized for certain mAb medications. Additionally, MDHHS has issued guidance on the use of the SC route of administration. Authorized EMS personnel should assure that the administration of mAb products are done in accordance with the applicable FDA Fact Sheet for Health Care Providers and applicable guidance by MDHHS.
D. Perform administration as directed in the appropriate Fact Sheet for Healthcare Provider.
E. If applicable, discontinue the infusion and flush IV with 10 mL of NSS, keeping the IV in place during monitoring period.
F. Treat any significant mAb administration related symptoms (e.g., nausea, fever, etc.) in accordance with appropriate approved protocols and/or prescribers orders consistent with the EMS personnel's scope of practice.

IV. Monitoring and Administration Related Problems
A. Full vital signs should be obtained prior to beginning the administration.
B. For patients with vital signs within normal limits, vital signs should be monitored at least every 30 minutes during the administration and post-administration observation period.
C. For patients that have or develop any abnormal vital signs or experience any side effects, vital signs must be recorded at least every 15 minutes.
D. If a patient has minor symptoms during the administration
    i. Slow the rate of infusion (if applicable)
    ii. If symptoms do not improve, treat per appropriate protocols and consider discontinuing the administration.
    iii. If symptoms worsen, stop administration and contact prescribing health care provider or medical control.
E. If a patient has significant symptoms that appear to be administration-related, immediately discontinue the administration and contact the prescribing health care provider or medical control.
F. All patients must be monitored, as above, for at least 60 minutes after completing or discontinuing the administration. This monitoring and observation period may be

conducted by a Medical First Responder if immediate assistance is available from an EMT-Basic with appropriate BLS equipment immediately available.

G. At the conclusion of the 60-minute observation period, and:
   i. If there have been no changes in the patient's vitals, or the patient has improved since initial assessment, no contact with medical control is necessary. The patient may be released, with instructions to seek medical assistance or contact 911 if symptoms worsen.
   ii. If there are changes in the patient's status, but they have resolved/improved, consider making contact with the ordering clinician and advising of administration related symptoms and status. The patient may be released, with instructions to seek medical assistance or contact 911 if symptoms worsen.
   iii. If the patient experiences concerning or worsening symptoms (including COVID-19 related), provide continued care per appropriate protocols and transport to the hospital. Medical control must be contacted if the patient is refusing transport to the emergency department.

V. Documentation and Reporting

A. Any medication errors or serious adverse events must be reported to the prescribing health care provider and to the Medical Control Authority.

B. Electronic Patient Care Reports must be completed for each patient receiving administration of monoclonal antibody therapy administered by the authorized EMS personnel.
   i. Document vital signs, general assessment, and how the patient tolerates administration, including potential administration-related side effects or change in COVID-19 symptoms.
   ii. Document the lot number and expiration of the medication on order form and in narrative section of EMS patient care report.
   iii. In the narrative section document "MAB infused by EMS" or "MAB administered by EMS."

C. Additional Documentation
   i. Complete and submit the electronic Patient Profile Form
   ii. Assure that the ordering clinician receives a copy of the completed order form, EMS patient care record, and signed Fact Sheet for Patients, Parents, and Caregivers