Initial Date: 03/23/2020
Revised Date: 04/24/2020

Section: 14-01

## *Privileging and Participating Facilities Release During COVID-19 Response*

**Purpose:** Establish a mechanism allowing EMS agencies/Medical Control Authorities (MCA) to give prehospital care across jurisdictional boundaries during the COVID-19 response.

1. During the COVID-19 response all MCA, EMS Agencies, and Emergency Departments assist and support each other. This provides an approved/authorized process allowing EMS agencies to function within an MCA during the COVID-19 response.

2. Requests for support may be made to the MCA or EMS agencies within the state through each MCA's local Healthcare Coalition. Response is dependent on the availability of equipment and personnel.

3. For the purpose of load balancing hospitals during the COVID-19 pandemic, personnel and agencies from different MCAs will be allowed to operate in any MCA for the duration of the response.

    a. Personnel should function according to the protocols of their home MCA.
    b. When need diminishes, previously approved privileging protocols will be immediately reinstated.
    c. Agencies operating under this protocol during the COVID-19 response will return to their normal approved response areas when the need for cross-MCA function has lapsed.

MCA Name: Sanilac MCA
MCA Board Approval Date: 5/6/2020
MCA Implementation Date: 5/6/2020
Protocol Source/References:

## *Resource Utilization*

**Purpose:** To facilitate appropriate resource utilization in the EMS system.

I. Priority One and Two Responses*:
   a. First unit on scene should cancel any resources that have not made the scene that are not necessary. (Non-transporting agency should not wait for transporting vehicle to arrive for uncomplicated refusals or public assists)
   b. If BLS and ALS resources are available, they should be dual dispatched to incidents where an EMD dispatcher anticipates likelihood of a patient not requiring ALS care.
   c. A patient may be assessed by a paramedic and determined to be appropriate for transport by a BLS ambulance, if available.
      i. Criteria for BLS Transportation
         1. Patient has stable vital signs (pulse between 50 and 100, RR>12/<20, SBP>100/<180, SpO2 >94% on room air) and is alert **AND,**
         2. Patient does not (or is unlikely to) require ALS care while being transported to the hospital (BLS personnel may transport patient with saline lock) **AND,**
         3. Patient does not require cardiac monitoring (e.g., chest pain, dyspnea, syncope) **AND,**
         4. Arrival of BLS ambulance is likely to be less than the ALS transport time to the hospital.
   d. ALS to BLS Transfer of Care
      i. ALS personnel MUST provide BLS personnel with a complete hand-off including medical history, pertinent physical exam findings, vital signs, and treatment provided and response. (This can be in the form of a paper document or direct entry into an electronic record) A verbal report alone is not sufficient.
      ii. ALS Responsibilities
         1. Provide assessment and care consistent with appropriate protocol
         2. Assure patient meets criteria above
         3. Provide verbal and written hand-off to BLS personnel
         4. Remain with patient until transfer of care to BLS personnel. In the event of system overload where ALS is needed to respond to another emergency. ALS may transfer care to non-transporting BLS or MFR personnel temporarily provided:
            a. A BLS transporting unit is already enroute to the scene
            b. BLS non-transporting or MFR personnel are comfortable with level of care necessary
      iii. BLS Responsibilities
         1. Assure that patient meets clinical criteria
         2. Receive verbal and written handoff from ALS personnel and obtain any additional information prior to transport
         3. Provide continued BLS care consistent with protocol

4. In the event of an unanticipated medical emergency requiring ALS care, request an ALS intercept or continue to destination hospital alerting them as to change in condition (whichever provides most timely access to ALS care)
5. Provide verbal and written hand-off to hospital personnel
6. Document EMS encounter (including ALS component) per protocol

iv. Eligible Patient Examples

1. Minor trauma without concerning mechanism of injury or special trauma considerations (e.g., pregnant, blood thinners), and not needing ALS medications (e.g., analgesia)
2. Opioid overdose with successful reversal with naloxone and with stable vital signs and normal level of consciousness
3. Suspected alcohol intoxication with stable vital signs, alert, normal blood glucose, alert, no recent seizure, no evidence of trauma, no concern for co-toxins
4. Behavioral health condition with patient with stable vital signs, alert, and fully cooperative who have not required (or anticipated to need) physical or pharmacologic restraint
5. Patient was found hypoglycemic, has received ALS care resulting in normal level of consciousness, and not taking oral or long-acting anti-hyperglycemic medications.
6. Patients who have received analgesia (e.g., fentanyl IV/IN) and otherwise meet criteria
7. Note: Patients who meet above criteria who have a saline lock in place (no IV fluid infusion) who otherwise meet the above criteria may be transported by BLS

II. Priority Three**:

a. Solely BLS response is acceptable.
   i. An ALS ambulance will be dual-dispatched when EMS dispatch identifies potential need for pre-hospital analgesia based on information obtained from caller.
   ii. An ALS ambulance should be requested by BLS or MFR personnel on scene if patient found with moderate to severe pain
   iii. When a BLS unit is available within a 20-minute response time, ALS should not be dispatched to Priority 3 incidents even if an ALS unit is closer, provided analgesia not anticipated
   iv. A BLS ambulance may replace an ALS ambulance on incidents when on-scene non-transporting BLS or MFR personnel have determined the patient is not in need of ALS care
b. ALS will be requested by on scene MFR or BLS when patient does not meet the criteria for BLS transport

III. Use of BLS Ambulance when ALS not Readily Available

a. BLS ambulance should be dual dispatched to ALL critical incidents when closer than ALS, regardless of response times (cardiac arrest, trauma, stroke). The BLS ambulance will return to service when ALS has arrived and is no longer in need of BLS assistance.

b. For Priority 1 and 2 incidents where no ALS unit is available OR if the time interval for BLS response to hospital arrival is less than an ALS response time, a BLS ambulance should be dispatched to the scene.
c. BLS Responsibilities
    i. Provide care consistent with protocols
    ii. Determine if ALS intercept is indicated based on patient acuity, likely intervention, and transport time.
    iii. In the event of patient deterioration during treatment or transport, an ALS should be requested depending on the fastest time to ALS care. Cardiac arrests occurring during transport must be managed in a stationary ambulance, supported by closest first responders, and according to protocol with ALS intercept, if available.
    iv. Provide verbal and written hand-off to hospital personnel
    v. Document patient encounter in electronic patient care record

IV. Quality Improvement and Reporting
a. All BLS responses occurring under this protocol will be reviewed by the EMS agency and reported weekly to the MCA.
b. Sentinel Event: Any BLS response under this emergency protocol to a Priority 1 or 2 incident without ALS or to a Priority 3 incident resulting in a need for ALS care, and/or any emergency transport to the hospital will be considered to be a sentinel event and must be reported to the MCA by both the BLS personnel and by the agency (along with e-PCR) within 24 hours of the incident. EMS dispatch centers must document attempts/no availability of timely ALS resources for each occurrence under this protocol.

*Priority one includes patients with potential life-threatening emergencies including, but not limited to, shortness of breath, chest pain, and/or altered mental status. Priority two includes patients with serious illness or injury without immediate life-threatening conditions listed as priority one patients.
**Priority three includes patients with cough and/or sore throat but without other Priority one symptoms.

Initial Date: 02/12/2020

Revised Date: 05/16/2022 Section 14-05

## *Infection Prevention During the Coronavirus Disease (COVID-19) Pandemic*

**Purpose:** To outline infection prevention and personal protective actions when providing assessment and treatment during the COVID-19 pandemic. To outline the appropriate decontamination for people, equipment, and vehicles utilized in treatment and transport of patients.

Objective: To protect vulnerable patients being cared for by EMS and to protect the EMS workforce by reducing the transmission rate of COVID-19.

I. Each life support agency shall continuously monitor CDC Community Transmission Rates for each county they serve. Respiratory Protection should be based on CDC Community Transmission Rates for the county in which the EMS incident occurs as outlined below.
   a. EMS crews must be aware of CDC Community Transmission Rates at the start of every shift.
   b. CDC COVID-19 Community Levels do not apply to healthcare.

II. All patients should be evaluated for higher risk during the initial assessment. When in doubt, or if dispatch information matches higher risk patient criteria, treat patient as a higher risk patient.
   a. Higher Risk Patient
      i. Patient with known COVID-19 or close contact within ten days to a patient with known COVID-19
      ii. Patient is a resident or employee of a residential facility with a known current outbreak of COVID-19
      iii. Patient with any of the following signs or symptoms
         1. Dyspnea/shortness of breath (including asthma, COPD, CHF)
         2. Cough, sore throat, rhinorrhea (runny nose), fever/chills
         3. Myalgias (muscle aches)
         4. Patient in cardiac or respiratory arrest
         5. Any other circumstance in which EMS personnel believe patient may be at higher risk
   b. Lower Risk Patients are all other patients who do not meet higher risk criteria.

III. Universal Source Control
   a. Patients will have a surgical mask applied prior to being placed in an ambulance unless they are receiving oxygen by mask.



Protocol Source/References: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html, https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html, https://www.cdc.gov/infectioncontrol/guidelines/isolation/precautions.html

b. Anyone accompanying the patient in any part of the ambulance regardless of COVID-19 symptoms will minimally have a surgical mask applied prior to entering the ambulance.

IV. All patient contacts include:

a. Protective equipment according to bodily fluid exposure, per MIOSHA standards.

b. Respiratory protection as outlined below.

V. Guidance for respiratory protection utilization based on situation

| Community Transmission Level | Lower-Risk Patient Outside Ambulance[1]/Not Close[2] | Lower-Risk Patient Inside Ambulance[1]/ Close[2] | Higher-Risk Patient Not Inside Ambulance[1]/ Not Close[2] | Higher-Risk Patient Inside of Ambulance[1]/ Close[2] |
|---|---|---|---|---|
| Low | ≥Surgical Mask | ≥Surgical Mask | ≥Surgical Mask | ≥N95 |
| Moderate | ≥Surgical Mask | ≥Surgical Mask | ≥N95? | ≥N95 |
| Substantial | ≥Surgical Mask | ≥N95 | ≥N95 | ≥N95 |
| High | ≥Surgical Mask | ≥N95 | ≥N95 | ≥N95 |

[1]Refers to patient care compartment of ambulance.
[2]Close refers to within 3 feet of patient or in any area with decreased air flow

VI. During Treatment

a. The number of responders within six feet of the patient should be limited to the fewest number to provide essential patient care.

b. A (surgical type) facemask should be placed on the patient for source control. Do not place N-95 or similar masks on patients as these increase the work of breathing.

c. Any family or bystanders should not be within six feet of responders, and if they are, they need to wear at least a surgical face mask.

d. Aerosol Generating Procedures

i. Perform aerosol-generating procedures using PPE in accordance with MIOSHA requirements for healthcare providers.

ii. Perform aerosol-generating procedures only when clinically indicated. iii. Keep patient and aerosolization away from others without PPE (e.g., bystanders, EMS personnel not in PPE, etc.).

iv. Preferably, aerosolized procedures should NOT be done within the ambulance. When treating patient in the ambulance, activate patient compartment exhaust fan at maximum level.

v. Use HEPA filtration for expired air from the patient (Ventilators, CPAP, biPAP, BVM).

VII. Patient Compartment –



Protocol Source/References: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html, https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html, https://www.cdc.gov/infectioncontrol/guidelines/isolation/precautions.html

a. When practical, utilize a vehicle with an isolated driver and patient compartment.
b. Only necessary personnel should be in the patient compartment with the patient.
c. All compartments should have ventilation maintained, with outside air vents open and set to non-recirculated mode.

VIII. Patient Transfer of Higher Risk Patient

a. Friends and family of the patient should avoid not riding in the transport vehicle with the patient. If they must accompany the patient, they will minimally have a surgical mask applied.
b. Personnel driving the transport vehicle should doff PPE (except for respiratory protection) and perform hand hygiene before entering the driver's compartment. Respiratory protection should be maintained throughout.
c. Ventilation in the driver's compartment should be set to bring in outside air and on maximum speed.
d. Notification of infectious risk (if known) should be made to receiving facility as soon as feasible.
e. Upon arrival at receiving facility, open patient compartment doors BEFORE opening driver's compartment doors.
f. Maintain mask on patient and filtered exhaust while transporting patient to room.
g. Patients should never be transported into a hospital with a nebulizer treatment in progress, regardless of COVID-19 patient status.
h. If patient care requires CPAP, contact receiving hospital to coordinate hand-off in a manner that minimizes hospital environmental risk.
i. Avoid transporting the patient within 6 feet of others (e.g., unprotected hospital staff, patients, bystanders, etc.)
j. Minimize delays in moving symptomatic (or confirmed/suspected or patients with respiratory symptoms) directly to a room to limit exposure to others (e.g., hallway passerby).
k. Higher risk patients should not be taken to the waiting room/triage area.
l. Doff PPE after leaving patient room and perform hand hygiene before touching documentation tools.

IX. Cleaning of Transport Vehicle and Equipment After Each Transfer

a. All equipment that was involved in patient care and equipment that was inside of patient compartment of ambulance should be cleaned, regardless of COVID-19 patient status.
b. Ambulances should be thoroughly cleaned (including door/compartment handles and ambulance cab) at the beginning and end of each shift in which patient transport occurred, regardless of COVID-19 patient status.



Protocol Source/References: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html, https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html, https://www.cdc.gov/infectioncontrol/guidelines/isolation/precautions.html

c. Vehicle disinfection should include door handles, steering wheel, and other surfaces contacted by personnel. Electrostatic disinfecting systems (or comparable disinfecting system) should be used when available.
d. Perform hand hygiene after cleaning is complete and PPE doffed and disposed of.



Protocol Source/References: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html, https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html, https://www.cdc.gov/infectioncontrol/guidelines/isolation/precautions.html

## *Clinical Treatment for Patient with Suspected or Confirmed COVID-19*

I. Applicable patients:

Patients prescreened or encountered by EMS personnel who may or may not have been pre-identified by 911/EMD as a potential COVID-19 patient:

A. Have signs and symptoms of respiratory illness (cough, shortness of breath)
B. Have signs and symptoms of respiratory illness (cough, shortness of breath) AND known exposure to patient with suspected COVID-19
C. Have other signs or symptoms associated with COVID-19 (fever, chills, shaking with chills, sore throat, loss of sense of taste/smell, muscle pain, headache, profound fatigue).

II. Personal Protective Equipment:

A. Standard, contact, and airborne precautions
B. Surgical masks for personnel may be substituted for N95 masks when no aerosolized procedures are taking place and when not in an enclosed area (e.g. ambulance patient compartment) with actively coughing patient.
C. Surgical masks or non-rebreather masks with supplemental oxygen for patients in respiratory distress should be applied to the patient whenever possible to perform source control. All patients regardless of COVID-19 suspicion should have surgical mask applied for source control.

III. Treatment:

A. Follow General Prehospital Care Protocol and other applicable protocols modified as below
B. Patients should receive oxygen to maintain SPO2 ≥94%
    i. Nasal cannula should be applied under a surgical mask.
    ii. Non-rebreather masks, for patients with hypoxia or respiratory distress should be used in lieu of surgical masks.
    iii. Combined nasal cannula at 6 LPM and non-rebreather mask at 12-15 LPM may be considered in patients remaining hypoxic after non-rebreather alone.
C. Assess breath sounds
    i. For patients with clear breath sounds, continue supportive oxygenation.
    ii. For patients with wheezing
        1. Preferred mechanism for pharmacological intervention is albuterol by metered dose inhaler (MDI) with spacer (including assisting patient with personal inhaler of albuterol), if available.
            a. Administer 4 puffs over 30-60 seconds (equivalent to 2.5 mg of albuterol)
            b. Dose may be repeated as needed every 5 minutes.
        2. If patient has wheezing with moderate to severe dyspnea and there is not access to MDI and the patient has a known history of asthma/COPD
            a. Administer bronchodilator via nebulizer in open area with maximum air ventilation, with N95 or greater respirator applied to personnel, and single rescuer monitoring patient from maximal distance possible. Contact medical control for direction, as needed.

b. **DO NOT** administer nebulized medication in closed ambulance.
c. For patients with known history of asthma/COPD and in moderate to severe dyspnea WITH wheezing, may administer: epinephrine (1 mg per mL) 0.3 mL IM. (Skill may be BLS or MFR, depending on MCA selection.)

iii. For patients with severe respiratory distress AND a history of CHF or COPD and positioning, oxygenation, and other treatments (e.g. nitroglycerin 0.4 mg SL q 3 minutes for CHF) are not effective:
1. Apply CPAP per protocol.
2. Use HEPA filter for exhalation port, if available.
3. CPAP being utilized in the patient compartment should be limited to necessity and only when all providers in the patient compartment have N95 respirators in place.
4. Contact receiving hospital as early as possible to advise them of patient requiring CPAP to allow for appropriate transition of care upon arrival.

D. Hypotensive patients – those with SBP <90mmHg with signs and symptoms of shock
i. Administer normal saline 250 mL bolus.
ii. Reassess BP and signs and symptoms of shock prior to administering more fluid
iii. Normal saline boluses of 250 mL may be repeated to a maximum of one liter as signs/symptoms persist before contacting medical control.

E. Airway management
i. **DO NOT** intubate or perform (mouth to mask/mouth) rescue breathing on patients with suspected COVID-19.
ii. Utilize supraglottic airways with ETCO2 if an advanced airway needs to be placed.
iii. Place filter inline for ventilations or utilize a BVM with filtration capability, if available.

IV. Time sensitive patients:
A. Patients in need of immediate intervention will be treated with a minimum of gloves, eye protection, and mask

V. Transport:
A. Interventions should be performed **PRIOR** to loading into or closing patient compartment of the ambulance.
B. Only one provider will remain with patient for transport, if possible.
C. Follow COVID-19 Destination and Transport Protocol

VI. **Cardiac arrest- Follow CARDIAC ARREST IN A PATIENT WITH SUSPECTED COVID-19**

## *Nasopharyngeal Specimen Collection for COVID-19*

I. Applicable patients: Patients who have received a referral or order from a clinician (primary care, local health department, medical control physician) for specimen collection.

II. Collection Procedure for Nasal Pharyngeal Sampling:
- A. Don appropriate PPE
  - i. N95 Mask
  - ii. Gown
  - iii. Gloves
  - iv. Eye protection
- B. Place patient in seated position
- C. Tilt patient's head back slightly to visualize nasal passages
- D. Ask patient to remove face mask and close eyes
- E. Gently insert swab along nasal septum, just above the floor of the nasal passage, to the nasopharynx
  - i. Stop when resistance is met
  - ii. Do not force swab further
  - iii. If you detect resistance to the passage of the swab, back off and try reinserting it at a different angle, closer to the floor of the nasal canal.
  - iv. The swab should reach a depth equal to the distance from the nostrils to the outer opening of the ear.
- F. Rotate swab several times (keep in passage 10 seconds)
- G. Gently remove swab while rotating
- H. Place swab into collection tube according to directions
  - i. Place swab into tube before breaking stick
  - ii. Tighten cap securely
- I. Have patient reapply face mask

III. Packaging procedure:
- A. Label tube
  - i. Patient name
  - ii. Patient DOB
  - iii. Source
- B. Place tube in plastic bag with absorbent material
- C. Place sample in 95kPa bag
- D. Place bagged sample on ice pack
- E. Follow instructions according to referral source or ordering physician for shipping or delivery.

IV. Key Information:
- A. Uncomfortable procedure, be gentle with patient
- B. Questions or issues with packaging should be handled by referral source, according to directions on collection materials provided

Additional information and Video: https://www.nejm.org/doi/full/10.1056/NEJMvcm2010260

## *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

# Monoclonal Antibody Treatment and Post-Exposure Prophylaxis (PEP)
# Order Form for Patients ≥ 12 Years Old

| PATIENT NAME: | DOB: |
|---|---|
| ALLERGIES: | POSITIVE COVID-19 TEST ON*: |
| FDA PATIENT FACT SHEET PROVIDED ON:<br>* Not applicable for post-exposure prophylaxis use<br>** Per FDA EUA, patient education and patient fact sheet must be provided to the patient prior to administration. | |

## PATIENT SCREENING

- ☐ Age (≥ 12 y.o.): _____ (Required)
- ☐ Weight (≥ 40 kg): _____ (Required)
- ☐ **Mild to moderate COVID-19**; high-risk for progressing to severe COVID-19 and/or hospitalization (see below), positive test (antigen or PCR), within 10 days of symptom onset **OR**
- ☐ **Post-Exposure Prophylaxis (PEP)**, patient meets all of the following:
  - ☐ High-risk for progressing to severe COVID-19 and/or hospitalization (see below) **AND**
  - ☐ Vaccination status (one of the following) **AND**
    - ☐ Not fully vaccinated **OR**
    - ☐ Not expected to mount an adequate immune response to complete vaccination
  - ☐ Exposure risk
    - ☐ Exposure to COVID-19 positive individual as defined in CDC close contact criteria **OR**
    - ☐ At high risk of exposure to infected individuals in a residential setting

**Patient meets at least one of the following high-risk criteria:**

- ☐ Is ≥ 65 years of age
- ☐ Has a body mass index (BMI) ≥ 25
- ☐ Pregnancy
- ☐ Has chronic kidney disease
- ☐ Has diabetes
- ☐ Has immunosuppressive disease
- ☐ Is currently receiving immunosuppressive treatment
- ☐ Cardiovascular disease or hypertension
- ☐ Chronic lung diseases
- ☐ Neurodevelopmental disorders or other conditions that confer medical complexity
- ☐ Sickle cell disease
- ☐ Having a medical-related technological dependence not related to COVID-19 (e.g., tracheostomy, gastrostomy)
- ☐ Is 12-17 years of age and has: BMI ≥ 85th percentile for their age and gender based on CDC growth charts; sickle cell disease; congenital or acquired heart disease; neurodevelopmental disorders; medical related technological dependence; OR asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
- ☐ Other medical conditions or factors that place the patient at high risk for progressing to severe COVID-19
  Describe: _____

**Monoclonal Antibodies are NOT AUTHORIZED for use in patients** who are hospitalized due to COVID-19, OR who require oxygen therapy due to COVID-19, OR who require an increase in baseline oxygen flowrate due to COVID-19 for those on chronic oxygen therapy due to an underlying non-COVID-19 condition.

- ☐ Patient does not meet any of the above contraindications

**Monoclonal Antibody Therapy is NOT AUTHORIZED for pre-exposure prophylaxis. Only REGEN-COV (casirivimab + imdevimab) and bamlanivimab + etesevimab have Emergency Use Authorization for post-exposure prophylaxis, sotrovimab does not. Administration of monoclonal antibody for post-exposure prophylaxis is NOT A SUBSTITUTE for COVID-19 vaccination.**



Developed 12/10/2020
Revised 10/29/2021

## Drug and Administration for TREATMENT of Mild to Moderate COVID-19

☐ **REGEN-COV Treatment:** 600 mg casirivimab and 600 mg imdevimab. Per EUA, add 10 mL of co-formulated casirivimab and imdevimab OR add 5 mL of casirivimab and imdevimab to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet. Alternatively, may administer subcutaneously (SC) using four 2.5 mL injections as instructed in Health Care Providers Fact Sheet.

[a] Using individual vials, add 5 mL of casirivimab and 5 mL of imdevimab to a prefilled infusion bag.

[b] For treatment, IV infusion is strongly recommended. SC injection is an alternative route when IV infusion is not clinically or operationally feasible and would lead to delay in treatment.

☐ **Bamlanivimab/etesevimab Treatment:** 700 mg bamlanivimab and 1,400 mg of etesevimab. Per EUA, bamlanivimab and etesevimab must be diluted together as a single intravenous infusion. Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet.

[a] The minimum infusion time for patients weighing between 40 and 50 kg who are administered bamlanivimab and etesevimab together using the 250 mL prefilled 0.9% Sodium Chloride infusion bag must be extended to at least 70 minutes to ensure safe use (endotoxin load).

☐ **Sotrovimab Treatment:** 500 mg sotrovimab. Per EUA, remove one vial of sotrovimab from refrigerator and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes. Gently swirl vial (DO NOT SHAKE) before use without creating air bubbles. Add 8mL of sotrovimab (1 vial) to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Provider Fact Sheet.

[a] Sotrovimab is a clear, colorless, or yellow to brown solution. Discard if particulate matter or discoloration is observed prior to administration.

[b] Prior to infusion, gently rock the infusion bag back and forth by hand for 3 to 5 minutes. Avoid forming air bubbles.

## Drug and Administration for POST-EXPOSURE PROPHYLAXIS (PEP)

☐ **REGEN-COV, initial PEP:** 600 mg casirivimab and 600 mg imdevimab. Per EUA, add 10 mL of co-formulated casirivimab and imdevimab OR add 5 mL of casirivimab and imdevimab to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet. Alternatively, may administer subcutaneously (SC) using four 2.5 mL injections as instructed in Health Care Providers Fact Sheet.

[a] Using individual vials, add 5 mL of casirivimab and 5 mL of imdevimab to a prefilled infusion bag.

[b] For post-exposure prophylaxis, either SC injection or IV infusion can be used per Health Care Providers Fact Sheet.

☐ **REGEN-COV, repeat dose PEP:** 300 mg casirivimab and 300 mg imdevimab. Per EUA, add 5 mL of co-formulated casirivimab and imdevimab OR dilute individual vials of casirivimab and imdevimab (see below) to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet. Alternatively, may administer subcutaneously (SC) using two 2.5 mL injections as instructed in Health Care Providers Fact Sheet.

[a] Using individual vials, add 2.5 mL of casirivimab and 2.5 mL of imdevimab for a total of 5 mL to a prefilled infusion bag

[b] Subsequent repeat dosing every 4 weeks after initial 600 mg casirivimab and 600 mg imdevimab dosing for the duration of ongoing exposure

[c] For post-exposure prophylaxis, either SC injection or IV infusion can be used per Health Care Provider Fact Sheet.

☐ **Bamlanivimab/etesevimab PEP:** 700 mg bamlanivimab and 1,400 mg of etesevimab. Per EUA, bamlanivimab and etesevimab must be diluted together as a single intravenous infusion. Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet.

[a] The minimum infusion time for patients weighing less than 50 kg who are administered bamlanivimab and etesevimab together using the 250 mL prefilled 0.9% Sodium Chloride infusion bag must be extended to at least 70 minutes to ensure safe use (endotoxin load).

***To be documented at time of administration:***

**Casirivimab LOT Number:** _____ **Expiration Date:** _____

**Imdevimab LOT Number:** _____ **Expiration Date:** _____

**Bamlanivimab LOT Number:** _____ **Expiration Date:** _____

**Etesevimab LOT Number:** _____ **Expiration Date:** _____

**Sotrovimab Lot Number:** _____ **Expiration Date** _____

_____

**Administering Provider** **Signature** **Date**



Developed 12/10/2020
Revised 10/29/2021

## POST-INFUSION

- ☐ Flush administration set with 0.9% sodium chloride to deliver residual volume.
- ☐ Leave IV in place for observation period; remove prior to discharge.
- ☐ Monitor patient for hypersensitivity reaction for a period of 60 minutes following infusion.
- ☐ Send record of treatment and post infusion summary (page 3) to prescriber at fax number below

## MANAGEMENT OF HYPERSENSITIVITY

Patients must be clinically monitored during infusion and observed for at least one hour after infusion is complete. Vital signs must be measure before infusion and ≤ q 30 minutes, and when indicated until conclusion of observation period.

| **Management of Minor Infusion-Related Symptoms** | |
|---|---|
| Nausea/Vomiting | ☐ Ondansetron (Zofran): 4 mg ODT (oral dissolving tablet) or 4 mg IV |
| Headache/Fever | ☐ Acetaminophen: 650-1,000 mg PO |
| *** Minor infusion related symptoms such as nausea, headache, fever, and dizziness can often improve with slowing infusion rate. For minor symptoms early in the infusion, decrease infusion rate by 25-50%. | |
| **Management of Severe (anaphylactic and non-anaphylactic) Administration-Related Symptoms** | |
| *** Immediately stop infusion, obtain vital signs, initiate supplemental oxygen, as indicated. Activate the emergency medical system (EMS; e.g., call 911 if applicable) and notify the patient's physician/clinician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient and initiates treatment, as appropriate. | |
| **Management of Anaphylactic Symptoms** | |
| Anaphylaxis | ☐ **Epinephrine 0.3 mg IM (includes autoinjector); if signs of hypotension and/or respiratory distress with wheezes or stridor are present, repeat dose every 5 to 15 minutes for up to two doses and diphenhydramine as described below.**<br>☐ Diphenhydramine 50 mg IM or IV (administer alone for moderate symptoms) |
| *** Immediately stop infusion, obtain vital signs, initiate supplemental oxygen as indicated, administer medications as above, limit epinephrine to shock or severe respiratory distress. Call EMS and continue supportive care, while monitoring patient closely until arrival. Notify the prescribing physician/clinician as soon as able. | |

## ADDITIONAL ORDERS

## ORDERING PRESCRIBER

**Prescriber Name:** _____

**Prescriber Signature:** _____

**As the ordering prescriber, I allow for product selection and authorize the administering practitioner to substitute for another monoclonal antibody identified on this order form, unless the box below is checked.**

- ☐ **Dispense as written (DAW) *** checking DAW could result in significant delays in treatment based on availability of medication supplies *****

**Direct Contact Number:** (___) ___ – _____ **Fax Number:** (___) ___ – _____

**Order date:** _____ ☐ **Check if administered under a standing order**



Developed 12/10/2020
Revised 10/29/2021

## REPORTING REQUIREMENTS

In accordance with the Michigan Public Health Code (MCL 331.531), the following survey must be completed for each patient treated with monoclonal antibody (MAB) therapy supplied through the State of Michigan: https://forms.office.com/Pages/ResponsePage.aspx?id=sgF4Zzdipk67RItjfx6ergRINfmr3E1Njq-ZF3K4ysBUMjRaVE43VjM1MFJRTllCVzBMMk9HWVVBTiQlQCN0PWcu.

## POST ADMINISTRATION SUMMARY

☐ No administration related problems

**Additional Comments:**

**Patients, Parents and Caregivers EUA Resources:**

- ☐ Fact Sheet For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Casirivimab and Imdevimab for Coronavirus Disease 2019 (COIV-19): https://www.fda.gov/media/145612/download.
- ☐ Fact Sheet For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab for Coronavirus Disease 2019 (COVID-19): https://www.fda.gov/media/145803/download.
- ☐ Fact Sheet For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Sotrovimab for Coronavirus Disease 2019 (COVID-19): https://www.fda.gov/media/149533/download.

**Patient Consent:** by signing this I attest to have read, or had explained to me, the patient fact sheet for the monoclonal antibody that I am receiving and have been provided an opportunity to ask questions, which have been answered to my satisfaction. I understand the potential risks and benefits associated with monoclonal antibody therapy and agree to receive the administration of this medication.

| Form Completed by/Relationship to Patient | Signature | Date |
|---|---|---|

**Standing Orders:** Note if administration is done under a standing order issued by an authorized prescriber, the administering clinician should complete all applicable sections of this form in accordance with the Standing Order. The name of the prescriber issuing the Standing Order should be documented and the Standing Order box checked on Page 3.