Dayton MMRS

GMVEMSC

Greater Miami Valley EMS Council (GMVEMSC)
Just in Time Standing Order (JITSO)
SOTROVIMAB: COVID-19 Monoclonal Antibody Administration
1/5/2022 – Paramedics Only

Use of this JITSO is at the discretion of each agency and must be approved by the agency director and agency medical director. Monoclonal Antibody (mAb) administration is within the Ohio EMS scope of practice for the Paramedic level of certification only.

Paramedics are authorized, at the discretion of their agency, to administer mAbs in the following settings:

- At local (including hospital) or regional mAb administration sites.
- In congregate residential sites, especially those experiencing COVID-19 outbreaks.
- In homes and other locations including stations.

Delivering the therapy takes about two hours. **Sotrovimab must be administered after dilution by intravenous (IV) infusion.** Treatment with mAbs should be started as soon as possible after the patient receives a positive test result for SARS-CoV-2 and must be within 10 days of symptom onset.

Indications:

To receive mAbs, patients must meet all three of the following criteria:

- Age 12 and older experiencing mild to moderate COVID symptoms and
- Weigh at least 40 kg and meet criteria for being at high risk for progression to severe illness and
- Have had their first positive test for SARS-CoV-2 virus and onset of symptoms within the past 10 days.

Due to resource limitations, systems may modify internal criteria to prioritize mAbs effectively.

Risk factors for development of severe COVID include, but are not limited to:

- Older age (for example > 65 years of age)
- Obesity or being overweight (for example, adults with BMI ≥ 25, or if age 12-17, BMI > 85th percentile for their age and gender)
- Pregnancy
- Chronic kidney disease
- Diabetes

- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, COPD, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, or pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital abnormalities).
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]).
- Other medical conditions or factors (for example, race or ethnicity) that place a patient at high risk for progression to severe COVID-19.
- Authorization of mAb therapy is not limited to the medical conditions or factors listed above.

Contraindications

Sotrovimab is not authorized for use in patients:

- Persons who are not within the 10 days following symptom onset or positive COVID-19 test
- Who are hospitalized due to COVID-19; OR
- Who require oxygen therapy due to COVID-19; OR
- Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy; OR
- Who have received a prior dose of casirivimab and imdevimab, bamlanivimab and etesevimib, or **sotrovimab**.
- **Sotrovimab** is contraindicated in patients who have a history of anaphylaxis to **sotrovimab** or to any of the excipients in the formulation.

Medication Administration:

- ♦ Requires *physician* authorization for each patient. If mAb is ordered by another provider, EMS must have it countersigned by a physician.
- Wear appropriate PPE including gloves, eye, and face protection, and NIOSH-certified facepiece respirators or better (i.e., PAPRs).
- Provide the patient with the Fact Sheet and document their receipt of it. It can be downloaded here: https://www.fda.gov/media/149533/download
- Document that the therapy was discussed, and the Fact Sheet was given to the patient or caregiver, that the patient was informed of alternatives, and that monoclonal antibodies are administered under an emergency use authorization.
- Prior to infusion, have the patient take **acetaminophen** (e.g., **Tylenol®**) **975 or 1,000 mg**, and advise the patient to repeat the dose every six hours for the next 24 hours.
    - If over age 65, **use a dose of 650 mg.**
    - Do not use acetaminophen if the patient has a history of hypersensitivity or liver disease.

Dosage and Administration:

- The dosage of **sotrovimab** in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is a single **intravenous (IV) infusion of 500 mg.**
- **Sotrovimab must be diluted and administered as a single IV infusion over 30 minutes**
    - IV access may be difficult in some mAb patients (e.g., elderly) and may require IV catheters as small as 24 gauge (which will slow fluid flows). Existing venous access (e.g., PICC lines) may also be used to deliver mAbs.

Dose Preparation and Administration:

Preparation

- **Sotrovimab** is supplied in a single-dose vial and must be diluted prior to administration.
- Gather the materials for preparation:
    - Choose from:
        - 50-mL or 100-mL infusion bag of 0.9% Sodium Chloride, or
        - 50-mL or 100-mL infusion bag of 5% Dextrose, and
    - One vial of **sotrovimab** (500 mg/8 mL).
- Remove one vial of **sotrovimab** from refrigerated storage and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes.
- Inspect the vial of **sotrovimab** visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded, and fresh solution prepared. **Sotrovimab** is a clear, colorless, or yellow to brown solution.
- Gently swirl the vial several times before use without creating air bubbles. **Do not shake the vial.**
- Withdraw 8 mL of **sotrovimab** from one vial and inject into the prefilled infusion bag.
- Discard any product remaining in the vial.
- Prior to the infusion, **gently rock the infusion bag back and forth by hand 3 to 5 times**. **Do not invert the infusion bag.** Avoid forming air bubbles.
- This product is preservative-free; therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted solution of **sotrovimab** up to 6 hours at room temperature (up to 77°F) or refrigerated up to 24 hours (36°F to 46°F).

Administration

- Gather the materials for infusion:
    - Infusion set, and
    - A 0.2-micron filter.
- Attach the infusion set to the IV bag using **standard bore tubing**.
- Prime the infusion set.
- Administer the entire infusion solution in the bag for **30 minutes**. Due to potential overfill of prefilled saline bags, the entire infusion solution in the bag should be

administered to avoid underdosage.

- **Do not administer as an IV push or bolus.**
- The prepared infusion solution should **not** be administered simultaneously with any other medication.
- Once infusion is complete, **flush the tubing** with 0.9% Sodium Chloride or 5% Dextrose to ensure delivery of the required dose.
- If the infusion must be discontinued due to an infusion reaction, discard unused product.
- **Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete.**

Management of adverse reactions:

Patients should be monitored during infusion and observe patients for at least 1 hour after infusion is completed.

- Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of **sotrovimab**. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive care.
- Infusion-related reactions, occurring during the infusion and up to 24 hours after the infusion, have been observed with administration of **sotrovimab**. These reactions may be severe or life threatening.
- Signs and symptoms of infusion-related reactions may include:
    - fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrial fibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vaso-vagal reactions (e.g., presyncope, syncope), dizziness, and diaphoresis.
- Consider slowing or stopping the infusion and administer appropriate medications and/or supportive care if an infusion-related reaction occurs.

Equipment – *None of the below are provided by the Regional Hub for mAbs*

- Each site must have IV supplies and a GMVEMSC Drug Bag (or equivalent medications for treating anaphylaxis: epinephrine, diphenhydramine, and an IV corticosteroid).
- Each site must have oxygen and delivery devices, and resuscitation equipment.
- PPE must include gloves, gowns, eye, and face protection, and NIOSH-certified facepiece respirators or better (i.e., PAPRs).
- Infusion supplies should include infusion pumps (if used), appropriately sized syringes, absorbent underpads (blue pads).
- Sharps container and biohazard disposal bag.
- IV tubing and Micropore **filter.**
- Locking refrigerator with temperature monitoring capability if stored onsite.
- Thermometer probe covers (if required).
- Acetaminophen (e.g. Tylenol®).

Storage and Handling:

- **Sotrovimab** is preservative-free. Discard any unused portion after use.
- Store unopened vials at 36°F to 46°F in the original carton to protect from light.
- DO NOT FREEZE
- DO NOT SHAKE
- DO NOT EXPOSE TO DIRECT LIGHT
- The prepared infusion solution is intended to be used immediately.
    - If immediate administration is not possible, store the diluted infusion solution for up to 24 hours at refrigerated temperature (36°F to 46°F) or up to 6 hours at room temperature (up to 77°F) including transportation and infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 15 minutes prior to administration

How Supplied for Use at EMS Sites other than hospitals or local/regional infusion centers

- The U.S. Government supplies **sotrovimab** for treatment and postexposure prophylaxis of COVID-19.
    - **This is only as supplies from the federal government are available.**
- EMS agencies planning to administer **sotrovimab** may obtain the drug from:
    - **Preferred method:** ODH has designated Miami Valley Hospital as a "Regional Hub" for mAbs. Regional hubs can obtain mAbs and distribute them to locations (including EMS agencies) using relatively small quantities.
        - Send an email with the completed "Premier Health Monoclonal Transfer Form" (attached) **to all four emails listed on the form:**
          gpkooken@premierhealth.com
          jmspicer@premierhealth.com
          lmharlow@premierhealth.com
          krbrooks@premierhealth.com
        - Phone contact is Lindsay Harlow, office phone 937-208-3206
            - Backup contact is Andrea Wintraub, office phone 937-208-2153
        - If there is an urgent need to obtain mAbs for administration and you are unable to reach the personnel above, contact the Regional MMRS Coordinator David Gerstner at 937-776-4410.
        - As listed on the Transfer Form, include the monoclonal being requested (**sotrovimab**), quantity requested, date of pick up, contact information, and attach a copy of your agency's State of Ohio license. Complete the "Transfer To:" section on the Monoclonal Transfer Form.
        - The **participating EMS agency must pick up mAbs** from Miami Valley Hospital. Deliveries of this medication cannot be made at this time.
        - mAbs provided from the Regional Hub at Miami Valley Hospital are not premixed. EMS will receive one vial per patient. The Regional Hub does not provide 100 cc bags of NS, filters, tubing, or bags of saline. Participating

EMS agencies **or other agencies** (e.g., long-term care facilities) will be required to provide this equipment.

In limited circumstances, EMS may be able to obtain mAbs through a different hospital. Contact the EMS Coordinator at the hospital to discuss that.

Monoclonal Transfer Form

Ordering Instructions

Email the following:

Gary Kooken (Buyer)	gpkooken@premierhealth.com
Jeannie Spicer (Buyer)	jmspicer@premierhealth.com
Lindsay Harlow (Manager)	lmharlow@premierhealth.com
Kevin Brooks (Director)	krbrooks@premierhealth.com

In the email indicate the following:

1. Monoclonal being requested
2. Quantity
3. Date of pick-up
4. Complete the "Transfer To" section below
5. Attach a copy of this Form and your State of Ohio license

TRANSFER FROM:	TRANSFER TO:
Name: Miami Valley Hospital	Name
Phone # (937) 208-2403	Phone #
Address: One Wyoming Street	Address
City: Dayton State: OH Zip: 45409	City State Zip
TDDD # 020035050	TDDD #

State of Ohio TDDD license has been verified, printed, and attached.

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GMVEMSC Monoclonal Antibody Administration

Patient Screening/Referral & Order Set Form for EMS Locations
At Local, Regional, or Hospital Centers: use form provided for that site

SOTROVIMAB EMERGENCY USE AUTHORIZATION SCREENING AND CONSENT FORM

SECTION 1: INFORMATION ABOUT PATIENT (PLEASE PRINT)

Name: Last:	First:	Middle Initial:
Date of Birth: Month Day Year	**Mobile Phone Number (Patient or Guardian): ( )**	
Email:		
Address:	**Apt/Room #:**	
City:	**State:**	**Zip:**
Name of Legal Guardian: Last:	First:	Middle Initial:

Sex (Gender assigned at birth)	**Race**	**Ethnicity**
☐ Female ☐ Male	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other ☐ Pacific Islander ☐ White ☐ Other Asian ☐ Other Nonwhite ☐ Other Pacific Islander ☐ Unknown	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Primary Insurance Carrier/Medicare/Medicaid ID #:_____ Grp #: _____
Insurance Company:_____ Insurance Company Phone #_____
Insured's Name:_____ Relationship:_____ Insured's Date of Birth_____
Secondary Insurance Carrier ID #:_____ Grp #: _____
Insurance Company:_____ Insurance Company Phone #_____
Insured's Name:_____ Relationship:_____ Insured's Date of Birth_____

SECTION 3: Authorizing Physician Information

Physician Name: _____ NPI #: _____

Office Name: _____ Physician Phone: _____ Physician Email/Fax: _____

SECTION 3: PATIENT SCREENING

Please check YES or No for each question.	**Yes**	**No**
1. Have you tested positive for and/or been diagnosed with COVID-19 infection within the last 10 days?		
If yes, what was the date of your positive test or onset of symptoms (whichever is earliest)?		
2. Have you been exposed to someone with known COVID-19?		
If yes, what was the date of this exposure?		
3. Have you had any COVID-19 antibody therapy within the last 28 days (for example, REGEN-COV, **sotrovimab**, bamlanivimab and etesevimab, COVID-19 convalescent plasma, etc.)?		
4. Are you 65 years of age or older?		
5. Are you overweight or have you been diagnosed with obesity (for example, is your BMI greater than 25 kg/m2, or if age 12- 17, is your BMI greater than or equal to the 85th percentile for your age and gender based on CDC growth charts)?		
How much do you weigh?		
6. Are you pregnant?		
7. Do you have chronic kidney disease?		
8. Do you have diabetes?		
9. Do you have immunosuppressive disease or are you receiving immunosuppressive treatment?		
10. Do you have cardiovascular disease (including congenital heart disease) or hypertension?		
11. Do you have sickle cell disease?		
12. Do you have a neurodevelopmental disorder (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)?		
13. Do you have any medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))?		
14. Do you have any other high-risk conditions, like chronic lung diseases, a stoma, or other high-risk diseases?		
If yes, describe:		
15. "Are you asymptomatic and unvaccinated, but have had a close COVID contact within the past 7 days?"		

- I certify that I am: (a) the patient and at least 12 years of age; (b) the legal guardian of the patient and confirm that the patient is at least 12 years of age; or (c) legally authorized to consent for administration of **sotrovimab** for the patient named above. Further, I hereby give my consent to receive **sotrovimab** for me or the patient named above.
- I understand that this product has not been approved or licensed by the FDA, but has been authorized for emergency use by the FDA, under an EUA for the treatment of mild or moderate coronavirus disease 2019 (COVID-19), and for post-exposure prophylaxis of COVID-19, in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-COV-2 viral testing, and/or known exposure to a household contact diagnosed with positive SARS-COV-2 viral test, and who are at high risk for progression to severe COVID-19, including hospitalization and death; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.
- I understand that it is not possible to predict all possible side effects or complications associated with receiving this treatment. I understand the risks and benefits associated with the above treatment and have received, read, and/or had explained to me the Emergency Use Authorization Fact Sheet. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction.
- I acknowledge that I have been advised to remain at the treatment location during the administration of **sotrovimab** and for at least 1 hour after completion of intravenous infusion. If I experience a severe reaction, I will be treated at the site or treated and transported to the nearest hospital.
- On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless the ***administering service*** and their staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the treatment listed above.
- I further authorize the ***administering service*** to submit a claim to my primary insurance carrier identified above on my behalf or on behalf of the patient named above for the administration of **sotrovimab**. I assign and request payment of authorized benefits to be made on my behalf to ***administering service*** with respect to the administration of **sotrovimab**. I understand that any payment for which I am financially responsible is due at the time of service or if ***administering service*** invoices, me after the time of service, upon receipt of such invoice.
- I acknowledge receipt of the Fact Sheet for Patients, Parents and Caregivers.

Signature of Patient or Authorized Representative_____ **Date:** _____

Print Name of Representative and Relationship to Person Receiving sotrovimab:_____

Site(s) (List all 4 for SQ) (RUE/LUE/RLE/LLE/RUQ/LUQ/RLQ/LLQ)	Route (IV)	Manufacturer (MVX)	Lot # Unit of Use/Unit of Sale	Expiration Date	Date of EUA Fact Sheet

Administered at location: facility name/ID	
Administered at location: Type	
Administration Address:	
Sending organization:	

Administering Service Name:_____ **Signature:**_____ **Date:** _____