Dayton MMRS

GMVEMSC

**Greater Miami Valley EMS Council (GMVEMSC)**

**Just in Time Standing Order (JITSO)**

# Regeneron: COVID-19 Monoclonal Antibody Administration

**12/14/2021 - 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. The intravenous route is strongly preferred for the treatment of symptomatic COVID-19, but subcutaneous administration is acceptable. 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. For Post-Exposure Prophylaxis (PEP), subcutaneous and intravenous administration are viewed as clinically equivalent. The **REGEN-COV (aka, Regeneron)** is a cocktail of two drugs (**casirivimab 600mg** and **imdevimab 600mg)**. Dosing is the same for treatment and for initial PEP.

**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)
- 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:**

REGEN-COV (aka, Regeneron) is not authorized for use in patients:

- Unless they can have the infusion or injections no later than 10 days after symptom onset and first positive test result; OR
- 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.

**Limitations of Authorized Use:**

- Post-Exposure Prophylaxis (PEP) with REGEN-COV is not a substitute for vaccination against COVID-19
- REGEN-COV is not authorized for pre-exposure prophylaxis to prevent COVID-19

**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/145612/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 or injection, have the patient take **acetaminophen** (e.g., **Tylenol**®) **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.
- Remove the **casirivimab** and **imdevimab** vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat. Do not shake the vial(s).
- Inspect **casirivimab** and **imdevimab** vial(s) visually for particulate matter and discoloration prior to administration. Should either be observed, the vial must be discarded, and a new vial must be used. The solution for each vial should be clear to slightly opalescent, colorless to pale yellow.
- Take vital signs including oxygen saturation before the start of infusion or subcutaneous injections. Do not start mAbs if the patient is hypotensive or has O2 levels < 90%.
    - Perform screening early. Some patients may be too ill (as indicated by vital signs and O2 sats to receive mAbs, and may even have to be transported to the hospital.
- Monitor the patient for 2-3 minutes after the start of the infusion or injections for any signs of hypersensitivity or allergic reactions such as:
    - Shortness of breath
    - Tightness in the chest
    - Glossal edema, angioedema, or periorbital or facial Edema
    - Hypotension
    - Rash/urticaria
    - Nausea/vomiting or diarrhea
    - Tachycardia
    - Lightheadedness/dizziness
- Clinically monitor patients after infusion/injections and observe patients for at least one hour. Document medication administration, patient assessments, and vital signs monitoring, including any adverse reactions.
- Consider **Ondansetron (Zofran)** 4 mg slow IV (preferred route) or 4 mg PO dissolving tablet for nausea or active vomiting.
- **Take vital signs every 15 minutes for 60 minutes after infusion or after completion of all four subcutaneous injections.**

**Preparation and Administration by INTRAVENOUS INFUSION**

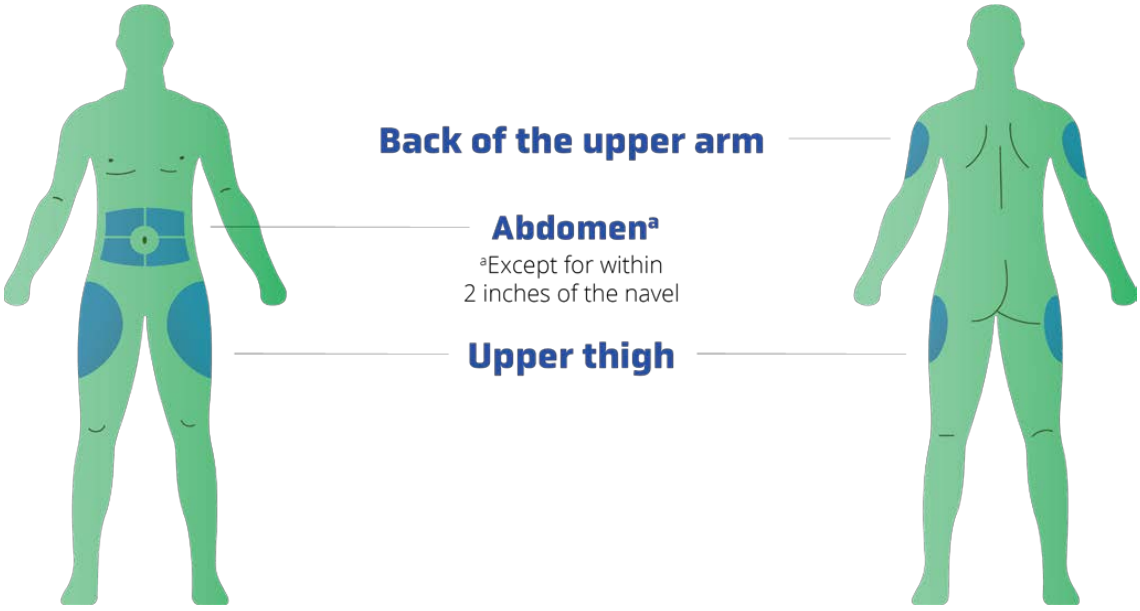
- Prepare infusion solution by placing **casirivimab 600mg** and **imdevimab 600mg** in an IV bag of Normal Saline or D5W.
    - IV access may be difficult in some mAb patients (e.g., elderly) and may require IV catheters as small as 24 gauge (which will slow fluid flows). Existing venous access (e.g., PICC lines) may also be used to deliver mAbs.

- The total volume of 110 mL is to be infused IVPB in a KVO primary line over 21 minutes (310 mL/hr).
    - If an infusion pump is not used, the microdrip tubing flow rate would be 315 drops per minute, which will be close to wide open. Monitor carefully to ensure that the infusion is delivered over not less than 21 minutes.
- Prime the medication IV bag with an infusion set containing **a 0.20 or 0.22 micron filter**.
- Administer casirivimab and imdevimab together as a single intravenous infusion via pump or gravity.
- Use only 0.9% Sodium Chloride or 5% Dextrose for infusion.
- The minimum time for an infusion of casirivimab and imdevimab together is <u>at least 20 minutes to ensure safe use</u>.
- Do not administer prepared solution simultaneously with any other medication.
- After the infusion is complete, flush the line with NS to ensure complete medication administration per protocol.

**<u>Preparation and Administration by SUBCUTANEOUS INJECTION</u>**

- Prepare **600 mg** of **casirivimab** and **600 mg** of **imdevimab** using four 3-mL or 5-mL polypropylene Luer lock syringes with 21- gauge, 1½-inch transfer needles.
- Withdraw 2.5 mL into each syringe (total of 4 syringes). Prepare all 4 syringes at the same time.
- ***If individual vials of casirivimab and imdevimab are being used, consider labeling syringes during preparation to ensure the two syringes of casirivimab and two syringes of imdevimab are identifiable.***
- Replace the 21-gauge transfer needle with a 25-gauge or 27- gauge needle for subcutaneous injection.
- The prepared syringes should be administered immediately. See <u>Storage and Handling</u> below.
- Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for two inches (5 cm) around the navel.
    - Avoid the waistline.
- Use different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of **casirivimab** and **imdevimab**.
- DO NOT inject into skin that is tender, damaged, bruised, or scarred.
- Subcutaneous mAb injection may not be appropriate in patients with poor skin perfusion, such as the elderly.

- Diagram of acceptable subcutaneous injection sites:




**Management of adverse reactions:**

Patients should be monitored during the IV infusion or SQ injections and for at least 1 hour after the infusion or injections are completed.

- The most commonly reported adverse event was nausea. Treat with **Ondansetron**.
- If signs of a clinically significant allergic reaction or anaphylaxis (as above) occur:
  - Stop infusion or do not administer additional subcutaneous injections.
  - Stay with the patient and activate transporting EMS agency.
  - Maintain patent airway and administer oxygen as needed per protocol.
  - Establish IV access and initiate cardiac monitoring.
  - Follow GMVEMSC Anaphylaxis protocol.
  - Consult online medical control as appropriate.
- Injection site reactions including ecchymosis and erythema were observed in up to 12% of patients receiving subcutaneous mAbs.

**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.

- Injection supplies should include 3-mL or 5-mL polypropylene Luer lock syringes, 21 gauge 1.5-inch transfer needles, and 25-gauge or 27-gauge needles for subcutaneous injection.
- Thermometer probe covers (if required).
- Acetaminophen (e.g. Tylenol®)

**Storage and Handling:**

- **Casirivimab** and **imdevimab** are preservative-free. Discard any unused portion after use.
- Store unopened vials in a refrigerator at 2ºC to 8°C (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 OR HEAT
- If given by intravenous infusion, solution in vial requires dilution prior to administration. The prepared infusion solution is intended to be used immediately.
    - If immediate administration is not possible, store diluted **casirivimab** and **imdevimab** solution:
        - in the refrigerator at 2ºC to 8ºC (36ºF to 46ºF) for no more than 36 hours. If refrigerated, allow the infusion to equilibrate to room temperature for approximately 30 minutes prior to administration.
        - or at room temperature up to 25ºC (77ºF) for no more than 4 hours. Reminder: store out of direct light or heat.
- If given by subcutaneous injection, the prepared syringes should be used immediately.
    - If immediate administration is not possible, store the prepared **casirivimab** and **imdevimab** syringes:
        - in the refrigerator at 2ºC to 8ºC (36ºF to 46ºF) for no more than 4 hours. If refrigerated, allow the syringes to equilibrate to room temperature for approximately 20 minutes prior to administration.
        - or at room temperature up to 25ºC (77ºF) for no more than 4 hours. Reminder: store out of direct light or heat.

**Post-Exposure Prophylaxis (PEP):**

- Indicated for individuals who are not fully vaccinated or who are not expected to mount an adequate immune response to SARS- CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) AND
    - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC OR
    - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons)
- Limitations of Authorized Use:
    - PEP with REGEN-COV is not a substitute for vaccination against COVID-19.

- REGEN-COV is **not** authorized for ***pre***-exposure prophylaxis for the prevention of COVID-19.

- The dosing and procedure are the same for PEP as for treatment (**casirivimab 600mg** and **imdevimab 600mg**), although subcutaneous and IV administration are considered equivalent for PEP.
  - If repeat dosing is needed for ongoing exposure, the subsequent repeat dosing is reduced to 300 mg of casirivimab and 300 mg of imdevimab by subcutaneous injection or intravenous infusion once every 4 weeks for the duration of exposure.

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

- The U.S. Government supplies **REGEN-COV** (**casirivimab** and **imdevimab**) for treatment and postexposure prophylaxis of COVID-19.
  - **This is only as supplies from the federal government are available.**
- EMS agencies planning to administer REGEN-COV 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 (Regeneron), 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 2 vials 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

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| TRANSFER FROM: | TRANSFER TO: |
|---|---|
| Name: Miami Valley Hospital | Name |
| Phone # (937) 208-2403 | Phone # |
| Address: One Wyoming Steet | 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**

## REGEN-COVTM (CASIRIVIMAB AND IMDEVIMAB) 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 | ☐ American Indian or Alaska Native | ☐ Native Hawaiian or other | ☐ Other Asian | ☐ Unknown | ☐ Hispanic or Latino |
| ☐ Male | ☐ Asian | ☐ Pacific Islander | ☐ Other Nonwhite | | ☐ Not Hispanic or Latino |
| | ☐ Black or African American | ☐ White | ☐ Other Pacific Islander | | ☐ 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 REGEN-COV for the patient named above. Further, I hereby give my consent to receive REGEN-COV 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 REGEN-COV and for at least 1 hour after completion of either intravenous infusion or subcutaneous injections, or as directed for observation. 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 REGEN-COV. I assign and request payment of authorized benefits to be made on my behalf to ***administering service*** with respect to the administration of REGEN-COV. 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 REGEN-COV:**_____

| Site(s) (List all 4 for SQ) (RUE/LUE/RLE/LLE/RUQ/LUQ/RLQ/LLQ) | Route (SQ/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:** _____