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**NOTE: This is a sample toolkit that facilities can use to customize to their needs or to develop their own site-specific protocols. It is not meant to represent formal guidance issued by the Illinois Department of Public Health (IDPH).**

**Purpose:**

Monoclonal antibody (mAb) therapy are treatments that may reduce the risk of severe COVID-19 disease and hospitalization. Monoclonal antibody treatment is indicated for persons with a positive COVID-19 test result, and for persons with a known exposure to COVID-19. The goal of this therapy is to reduce viral loads through neutralization of the COVID-19 virus, lessen symptom severity, and help prevent hospitalizations. Persons who may benefit from mAb treatments include those with risk factors for development of severe COVID-19 disease (below). Monoclonal antibody (mAb) treatments can currently be administered either by intravenous or subcutaneous routes.

**Who is eligible?**

Adult or pediatric (>12 years of age and weighing at least 40 kg) patients at high-risk for progressing to severe disease or death.

- **Treatment Dosing:** Patients who are COVID positive, with mild-to-moderate symptoms, not hospitalized due to COVID symptoms, and not requiring oxygen or an increase in home oxygen therapy are eligible, regardless of vaccination status.
- **Post-Exposure Prophylaxis (PEP):** Individuals who are not fully vaccinated or who are not expected to mount an adequate immune response to complete 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

**Risk factors for development of severe COVID include, but are not limited to:** (for both treatment and PEP indications)

- Older age (for example > 65 years of age)
- Obesity or being overweight (for example, adults with BMI  $\geq$  25, or if age 12-17, have BMI > 85th percentile for their age and gender based on CDC growth charts)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and 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) may also place individual patients at high risk for progression to severe COVID-19 and **authorization of mAb therapy is not limited to the medical conditions or factors listed above**. (For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, visit the [CDC](#) website).

### Procedure:

1) Identification of patients who may need mAb Therapy:

- a. **In outbreak settings:** Once the index (i.e., initial) case is identified, and SARS-CoV-2 testing is completed for all potentially exposed residents and staff, ideally within 48 hours, ALL positive residents could be offered mAb therapy within 10 days of their positive test result. All those who test negative and are either: (a) unvaccinated or (b) have any risk factor for progression to disease (see list of risk factors above) could be offered mAb therapy as post-exposure prophylaxis within 7 days of the exposure. If exposure dynamics are unknown, mAb therapy could be offered within 7 days from the test date of the index case.

**NOTE:** Residents and staff can receive mAb any time after receipt of COVID-19 vaccination. However, if they receive mAb first, it is feasible to defer vaccination by 90 days since the risk of re-infection is low in the 90 days after COVID-19 infection or receipt of passive antibody therapy. Per HHS, *Receipt of passive antibody therapy in the past 90 days is not a contraindication to receipt of COVID-19 vaccine. COVID-19 vaccine doses received within 90 days after receipt of passive antibody therapy do not need to be repeated.*

- b. **In non-outbreak settings:** Cases may be detected during SARS-CoV-2 testing of new admitted or symptomatic residents, and on unvaccinated staff at least weekly or more frequently based on community transmission levels, per current IDPH guidance for testing in long term care facilities.

People who test positive could be notified of their results in person at the congregate care facility or via phone (or telehealth clinic) by the ordering provider or primary care provider using current/existing notification practices. Monoclonal antibody (mAb) therapy could be offered to patients at that time. The following script for offering mAb therapy may be modified to suit the local and cultural needs of the population:

### INFORM RESIDENT/DECISION MAKER ABOUT MONOCLONAL ANTIBODY TREATMENT:

“I would like to let you know about some treatment options that may reduce your chances of getting severe illness or being hospitalized. This could also help the people you have been in close contact with, from getting COVID-19. You could get this treatment called monoclonal antibody or mAb, through an injection in the vein or under the skin. Also, you need to be aware that there may be no cost to the you for the antibody product itself since COVID-19 treatments are free. Depending on your insurance coverage, your insurance may be charged for the service,

but many large insurers are waiving all costs. Even if you do not have insurance, you may be able to have the treatment at no cost.”

**IF NOTIFIER’S LOCATION IS ADMINISTERING MONOCLONAL ANTIBODY TREATMENT AND CAN OFFER IT, INFORM THE PATIENT/DECISION MAKER AND PROCEED TO SCREENING (APPENDIX A) AS NEEDED.**

**IF NOTIFIER IS NOT ADMINISTERING MONOCLONAL ANTIBODY TREATMENT AND IS NOT THE PATIENT’S PROVIDER CONSIDER THE FOLLOWING SCRIPT:**

**“Should I get you set up for this treatment?”**

**Patient response: “Yes”**

**Notifier:** “Ok, great! Do you prefer to get the injection in a vein? We anticipate [XX] delay in getting the infusion set up but we can also give you this treatment through injections under the skin, without a similar delay.

First, we’ll go through a quick checklist to make sure this treatment is right for you”:

**PROCEED TO CHECKLIST ON NEXT PAGE (ALSO APPENDIX A)**

**NEXT PAGE HAS SCREENING CHECKLIST (APPENDIX A) FOR THOSE INTERESTED- If clinical staff are doing the result notification, they can proceed to screening. If clinical staff are not doing the notification, then the notifier transfers to a clinical staff where clinical checklist can be complete. If no transfer line available, then notifier will notify patient that the clinical team will be call them shortly to set up the next steps.**

**Patient response: “No, I am not interested.”**

**Notifier:** “Ok, if you change your mind in the next 10 days then you can let us know. Now timing is important because treatment needs to begin within 10 days after you start having symptoms. Even if you don’t have symptoms yet, call your medical provider (or inform the on-call staff who can notify our medical provider) so you are ready if symptoms develop.”

If you cannot reach your medical provider, you can call this number: *(Use local number if available)* or **1-800-889-3931** or email [dph.mabtherapy@illinois.gov](mailto:dph.mabtherapy@illinois.gov)

**IF NOTIFIER HAS NO LOCAL INFORMATION TO OFFER:** You can also call the national COVID call line and they can help you find the location nearest to you after you leave our facility (English line: 1-877-332-6585; Spanish line: 1-877-366-0310).

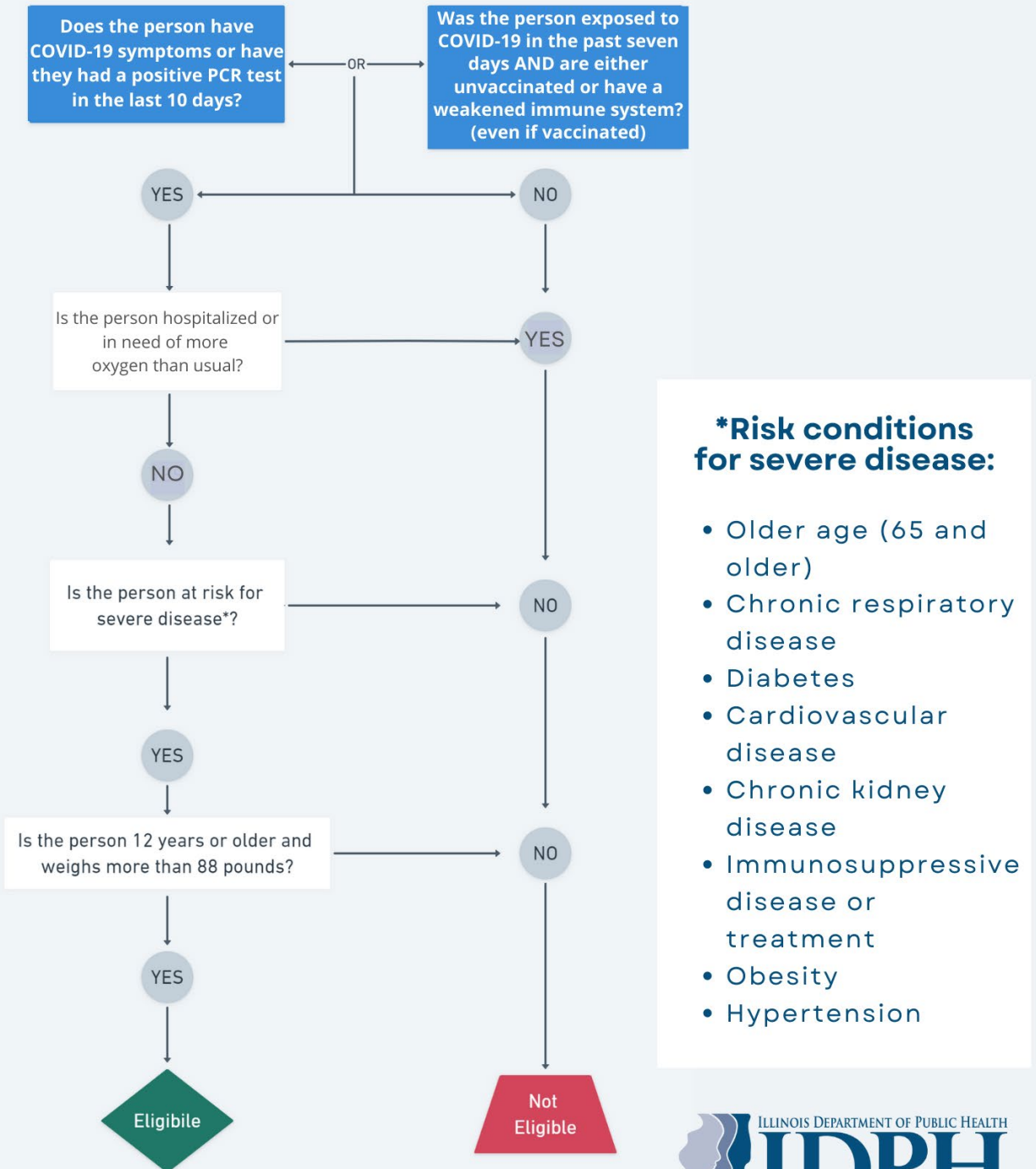
**Regeneron or Bamlanivimab plus Etesevimab (Bam/ete) for POST EXPOSURE PROPHYLAXIS or PEP**

Follow up script to determine if contacts will also be interested in Regeneron for post exposure prophylaxis:

**Notifier:** “Now that you’ve been exposed to COVID-19 – are you interested in getting this treatment to protect from getting severe COVID-19 infection? **You should get it within 7 days of being exposed to COVID-19.**”

**Patient/Decision Maker response: “Yes”**

## Eligibility for Monoclonal Antibody Treatment to Prevent Severe COVID-19



**\*Risk conditions for severe disease:**

- Older age (65 and older)
- Chronic respiratory disease
- Diabetes
- Cardiovascular disease
- Chronic kidney disease
- Immunosuppressive disease or treatment
- Obesity
- Hypertension



**APPENDIX A: COVID-19 Antibody Therapy Indication Checklist for Treatment (NOT Post Exposure Prophylaxis)**

This guide is intended to help inform appropriate prescribing for COVID-19 therapeutics in accordance with the Emergency Use Authorization (EUA), document clinical decision making and support medical necessity. This guide is not intended to supersede guidance from the CDC, state/local health departments, or other regulatory bodies. For complete information, refer to [combatcovid.hhs.gov](https://combatcovid.hhs.gov)

Criteria for Authorized Use – <b>Proceed if at least one box in EACH section is checked or marked</b>	
SECTION A: Positive results of direct SARS-CoV-2 viral testing (date of positive test result: _____) OR Date of symptom onset: _____. Should be given as soon as possible after a positive test and within 10 days of symptom onset	
SECTION B:	
<input type="checkbox"/> Mild COVID-19 <input type="checkbox"/> Signs and symptoms consistent with COVID-19 infection (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell). <input type="checkbox"/> Does not have shortness of breath, dyspnea on exertion, or abnormal imaging.	<input type="checkbox"/> Moderate COVID-19 <input type="checkbox"/> Evidence of lower respiratory disease during clinical assessment or imaging <input type="checkbox"/> SpO <sub>2</sub> ≥94% on room air at sea level <input type="checkbox"/> Respiratory rate ≤30 breaths/minute
<input type="checkbox"/> SECTION C: Weighs at least 40 kg (weight: _____)	
<input type="checkbox"/> SECTION D: At least 12 years of age: (age: _____)	
SECTION E: At high risk for progressing to severe COVID-19 and/or hospitalization due to the following:	
<input type="checkbox"/> Older age 65 years or older <input type="checkbox"/> Obesity <input type="checkbox"/> Adults: BMI >25 <input type="checkbox"/> Age 12-17 BMI ≥ 85th percentile <input type="checkbox"/> Pregnancy <input type="checkbox"/> Chronic kidney disease <input type="checkbox"/> Diabetes <input type="checkbox"/> Immunosuppressive disease or immunosuppressive treatments: <input type="checkbox"/> Sickle cell disease <input type="checkbox"/> Chronic lung disease (e.g., COPD, moderate- to-severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension)	<input type="checkbox"/> Cardiovascular disease (including congenital heart disease) or hypertension <input type="checkbox"/> Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic, or metabolic syndromes and severe congenital anomalies) <input type="checkbox"/> Having a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)) <input type="checkbox"/> Other medical conditions or factors (for example, race or ethnicity) that place individual at high risk for progression to severe COVID-19.
<p>The EUA is NOT limited to the medical conditions or factors listed above.            Healthcare providers should consider the benefit-risk for an individual patient.</p>	
<input type="checkbox"/> SECTION F: Does not require supplemental oxygen due to COVID-19 (or increase in baseline requirements if on chronic oxygen therapy unrelated to COVID-19)	

## **APPENDIX B: PROTOCOL FOR FOLLOW UP CLINICAL CARE OF PATIENTS IDENTIFIED FOR TREATMENT OR PROPHYLAXIS**

Consider a phone check-in or clinical follow up 24 hours and 7 days after receipt of infusion or Subq therapy.

Suggested checklist for phone triage on f/u at day 1 and day 7:

**Have you experienced any of the following in the past 24 hours?**

- Pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone
- Severe and constant pain or pressure in the chest
- Extreme difficulty breathing (such as gasping for air, being unable to talk without catching your (their) breath, severe wheezing, nostrils flaring, grunting, or using extra muscles around the chest to help breathe)
- New disorientation (acting confused)
- Unconscious or very difficult to wake up
- New or worsening seizures
- Signs of low blood pressure (too weak to stand, dizziness, lightheaded, feeling cold, pale, clammy skin)
- Dehydration (dry lips and mouth, not urinating much, sunken eyes)

**If YES to any of these then advise to call 911 or go to the emergency department if they report any life-threatening symptoms.**

**If no life-threatening symptoms, proceed with triage of mild to moderate symptoms**

- 1) Have you needed to go to an urgent care/ED or hospital since you've been sick (or been diagnosed with COVID)?
  - a. If yes, when did you go and what happened? (i.e. admitted to the hospital VS discharged)
- 2) How have you been feeling since you received the treatment? The better, same, worse?
- 3) Have you been experiencing worsening breathing or fatigue?
- 4) Have you had a way of checking your oxygen levels at home? If yes, what have the levels been? If <94% refer to urgent care or medical attention.
- 5) Have you needed to use more than usual of your asthma or COPD meds in the past week? If yes, refer for medical attention.

**Sites should track rates of hospital admissions of those who received treatment—ideally a monthly report that could be shared with the communities they serve.**



## **APPENDIX C: PROTOCOL FOR PROCURING, STORING AND ADMINISTERING mAb**

Facility where testing is done and where linked mAb is being offered will be responsible for procuring and storing mAb as follows:

### **Step 1: Ordering Product**

All sites that meet the requirements for administering monoclonal antibody therapeutics must order bamlanivimab/etesevimab (Lilly), REGEN-COV (Regeneron) or sotrovimab through IDPH who then orders it from AmerisourceBergen Corporation (ABC), the drugs' sole distributor. The products remain free of charge to requesting sites.

Please use the smartsheet link to make a request for product: [IDPH Monoclonal Antibody Request Form \(smartsheet.com\)](#)

You could also go to the [IDPH mAB website](#) for ordering information.

New sites that have never ordered mAB before should sign up using this [New Site form](#).

If you need mAB urgently, you could use the [matchmaker function](#) to find a local facility that could share doses or email [dph.mabtherapy@illinois.gov](mailto:dph.mabtherapy@illinois.gov) and IDPH could provide doses from its own stock.

### **Future Requests for product will follow this schedule:**

- 1) **Friday to Tuesday of Cycle week** – Providers allowed to make requests for upcoming cycle e.g. Cycle 9 – 11/8/2021 (Requested no later than 11/9/2021)  
Cycle 10 – 11/15/2021 (Requested no later than 11/16/2021)
- 2) **Tuesday to Thursday of Cycle week** – allocations released to states and local allocations will be determined based on requests and areas of need
- 3) **Friday** – allocations are entered in the AmeriSource Bergen Distribution Portal; SIREN Distribution to providers indicating allocation amounts

*Note: A request does not guarantee the amount of mAb requested will be provided or that the request will be approved. Priority will be based on areas of the state with the greatest need.*

### **Eligible sites are those that can:**

- Provide ABC with a board of pharmacy license or physician letter of authorization
- Attest to their designated class of trade and that they will administer the authorized product according to the terms of the FDA issued EUA
- Provide utilization data via either TeleTracking or NHSN

Sites can order product based on established minimum amounts; subsequent orders are subject to a maximum amount based on previous orders and utilization.

State departments of health will be informed of therapies ordered within their jurisdictions for awareness.

Please allow 1 to 2 days for product arrival following order placement. For new customers, please allow up to 2 days for the initial order following receipt of the required customer documentation. For any additional information regarding orders, product availability, or



access/log-in information, please email [c19therapies@amerisourcebergen.com](mailto:c19therapies@amerisourcebergen.com) or contact AmerisourceBergen's Customer Service Department.

## Step 2: Tracking Utilization

All sites that use monoclonal antibody therapeutics are required to report on utilization of the product every Wednesday. To learn more about your facility's reporting requirements, see the [process for tracking utilization of COVID-19 therapeutics](#).

Weekly reporting on use of federally purchased COVID-19 therapeutics **is required by every Monday**. Sites that use these therapies are required to report through HHS Protect, TeleTracking, or CDC's National Healthcare Safety Network (NHSN) depending on facility type. If you DON'T have a Teletracking account, one will be established for you at the time of your first order.

### Step 1: Registration

- Using the invitation link in your email (from: [hhs-protect@teletracking.com](mailto:hhs-protect@teletracking.com)), create a username and password<sup>1</sup>
- This link only works for the first use

### Step 2: Invite other team members

- This should be done if the responsibility to enter data will be shared across multiple people
- Visit <https://teletracking.protect.hhs.gov/> to invite additional data reporters

### Step 3: **Entering data into TeleTracking**

- For each of the products in the Therapeutics section, enter in quantity of product used in the last week and quantity remaining on hand and press submit
- The numbers should be in patient courses (e.g. number of patients that are treated/could be treated given available stock on hand)

<p><b>Casirivimab (REGN10933) / Imdevimab (REGN10987) (Therapeutic A)</b></p> <p>39a. Current inventory on hand (in courses) ⓘ</p> <input type="text" value="10"/>	<p><b>Bamlanivimab (Therapeutic B)</b></p> <p>39c. Current inventory on hand (in courses) ⓘ</p> <input type="text" value="15"/>
<p>39b. Courses used in the last week ⓘ</p> <input type="text" value="7"/>	<p>39d. Courses used in the last week ⓘ</p> <input type="text" value="Unknown"/>

Sites are required to enter administration and stock on hand data by Wednesday each week, compliance is tracked by TeleTracking and NHSN.

**For additional support (24/7):**

- Visit Teletracking website <https://help.cl-teletracking.com/en-us/c19/Therapeutics/Content/Home.htm>
- Email [hhs-protect@teletracking.com](mailto:hhs-protect@teletracking.com)
- Call 1-877-570-6903






**Step 5: Reimbursement and Coverage**

Reimbursement and coverage for monoclonal antibody therapeutics varies by provider.

- To learn about coverage under Medicare, Medicaid, and CHIP, see [Coverage of Monoclonal Antibody Products to Treat COVID-19](#)
- For specific instructions on Medicare payments and billing, see [Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction](#)
- To learn more about claims reimbursement for healthcare providers, see [HRSA’s FAQs for COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment and Vaccine Administration](#)

**CMS: Coverage of Monoclonal Antibody Products to Treat COVID-19**

**Medicare**

Site of Care <sup>1</sup>	Payable by Medicare	Expected Patient Cost-Sharing
Inpatient Hospital 	✓	No patient cost-sharing
Outpatient Hospital or "Hospital without Walls" <sup>2</sup> 	✓	No patient cost-sharing
Outpatient Physician Office/Infusion Center 	✓	No patient cost-sharing <sup>3</sup>
Nursing Home (See third bullet in Key Facts on CMS enforcement discretion) 	✓	No patient cost-sharing
Home 	✓	No patient cost-sharing

<sup>1</sup>Services must be furnished within the scope of the product's FDA authorization or approval and within the provider's scope of practice.  
<sup>2</sup>Under the Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.  
<sup>3</sup>Cost-sharing may apply to Medicare beneficiaries when they receive care from a provider that doesn't participate in Medicare.  
<sup>4</sup>Certain monoclonal antibody products to treat COVID-19 have been authorized under Food and Drug Administration Emergency Use Authorizations since November 10, 2020. More information including the level II HCPCS codes for the administration/infusion and post administration monitoring of these products can be found online in the Program Instruction.

**Expected Payment to Providers: Key Facts**

- Medicare payment for monoclonal antibody products to treat COVID-19 is similar across sites of care, with some small differences.
- Medicare pays for the administration of monoclonal antibody products to treat COVID-19. For example, Medicare will pay a national average of approximately \$450 for the administration of certain monoclonal antibody products<sup>4</sup>. Home infusion is reimbursed at a higher rate.
- CMS will exercise enforcement discretion to allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law to bill directly and receive direct reimbursement from the Medicare program for administering monoclonal antibody treatments to Medicare Part A Skilled Nursing Facility residents
- Medicare will pay the provider for these monoclonal antibody products when they are purchased by the provider. Medicare won't pay if the product is given to the provider for free by, for example, a government entity.
- When purchased by the provider, Medicare payment is typically at reasonable cost or at 95% of the Average Wholesale Price (an amount determined by the manufacturer). These payment amounts vary depending on which type of provider is supplying the product. Original Medicare will pay for these products for beneficiaries enrolled in Medicare Advantage.
- For more specific information about Medicare payments to providers for these monoclonal antibody products, please see these [Frequently Asked Questions](#).

[Additional information](https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf) can be found at <https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf>

**CMS Billing Codes**

**Regeneron product codes**

**Q0243:**

- Long descriptor: Injection, casirivimab and imdevimab, 2400 mg
- Short descriptor: casirivimab and imdevimab

**M0243:**

- Long Descriptor: intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring

- Short Descriptor: casirivimab and imdevimab infusion

M0244:

- Long Descriptor: intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring in the home or residence
- Short Descriptor: casirivi and imdevi infushome

**Bamla/ete codes**

- M0245: intravenous infusion, includes infusion and post administration monitoring
- M0246: same as above **but home infusion**

**Sotrovimab codes**

- M0247: Intravenous infusion, sotrovimab, includes infusion and post administration monitoring
- M0248: **home infusion**

**STORING/HANDLING AND ADMINISTRATION**

**Acceptable equipment for mAb drug storage at the Pharmacy:**

Functional pharmacy sink

Refrigerated storage (2-8°C)

Temperature control mechanism including temperature monitoring process

Product will be shipped refrigerated (2-8°C) to your location by USG distribution partners

Product should be stored refrigerated (2-8°C) before use

Target shelf-life for product ~10 months at minimum but can be extended to ~18 months,

follow guidance from manufacturer on expiration dates and product turnover

Prepared IV solutions are intended for immediate patient administration. If not used immediately:

Solutions may be held at refrigerated conditions for example:

- Eli Lilly no more than 24 hours
- Regeneron no more than 36 hours

Solutions may be held at ambient light and room temperature conditions (including preparation, solution hold, infusion and flush) for example:

- Eli Lilly no more than 7 hours
- Regeneron no more than 4 hours



**Prepared subcutaneous doses of Regeneron should be administered immediately. If not used immediately:**

**Syringes may be held at refrigerated conditions for no more than 4 hours and room temperature for no more than 4 total hours**

Please adhere to all guidelines for storage and use provided by manufacturer of EUA product. In addition to the packaging configurations noted above, some REGEN-COV™ carton and vial labels may have statements such as “Solution for Intravenous Administration” or “For Intravenous Infusion after Dilution”. **Any of these REGEN-COV™ vials may be used to prepare and administer intravenous infusions as well as subcutaneous injections, even though there is no language on the label that states the subcutaneous route is appropriate.**

**APPENDIX D: SAMPLE ORDER SET FOR SUBCUTANEOUS DOSING**

Patient Name:	Age:
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**REGEN-COV™ (Casirivimab + Imdevimab) SUBCUTANEOUS INJECTION Orders**

**Intravenous infusion is strongly recommended. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment.**

<b>Drug Allergies:</b>	<b>Weight:</b> (must weigh at least 40 kg)
<b>Date of Positive Test or exposure:</b>	<b>Date of Symptom Onset:</b>
<input type="checkbox"/> <b>Primary diagnosis:</b> U07.1 COVID-19 infection or Z20.822 Exposure to COVID-19	
<b>Diagnoses placing patient at high-risk for severe COVID-19 illness—include ICD-10 code(s) and description(s):</b>	
<b>Prescriber must indicate <i>all</i> of the following requirements have been met:</b>	
<input type="checkbox"/> Patient/caregiver has been given the Fact Sheet for Patients and Parents/Caregivers	
<input type="checkbox"/> Patient/caregiver has been informed of alternatives to receiving REGEN-COV™	
<input type="checkbox"/> Patient/caregiver has been informed that REGEN-COV™ is an unapproved product that is authorized for use under an Emergency Use Authorization.	

**Before Treatment:**

- Obtain baseline vital signs

- Hold REGEN-COV and initiate supportive treatment (e.g., supplemental oxygen) per facility protocol and prepare to transfer patient to higher level of care if patient exhibits severe COVID-19 symptoms or emergency warning signs including:
  - **SpO2 less than 94% on room air; respiratory rate greater than 30 breaths/min; lethargy; chest pain; new-onset confusion; or cyanosis.**

Treatment Orders:

- Withdraw a **total dose of casirivimab 600 mg/5 mL AND imdevimab 600 mg/5 mL** into **FOUR syringes**:
  - **TWO** syringes, each containing **casirivimab 300 mg/2.5 mL**; and,
  - **TWO** syringes, each containing **imdevimab 300 mg/2.5 mL**.
- Consecutively administer each syringe **subcutaneously** using a 25- or 27-gauge needle in a different injection site (thigh, back of arm, or abdomen except for 2 inches around navel), spacing injections apart and avoiding skin that is tender, damaged, bruised, or scarred.
- It is recommended that providers use different quadrants of the abdomen, upper thighs, or back of the upper arms to space apart each injection**

**Post-treatment:**

- Monitor patient for hypersensitivity reaction for a period of 60 minutes following injections.
- If adverse reaction occurs, treat per orders/protocol as clinically indicated.
- Record vital signs immediately following injections and prior to discharge.
- Provide patient with discharge instructions.
- Send record of treatment to prescriber at fax number below.

Prescriber Name (print): \_\_\_\_\_ Fax: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Additional details in the EUA guidance documents below:

Baml/ete: <https://www.fda.gov/media/145802/download>

Regencov (Casiri/imde): <https://www.fda.gov/media/145611/download>

Sotrovimab: <http://infusioncenter.org/wp-content/uploads/2021/06/SOTROVIMAB-EUA.pdf>

**PLEASE ENSURE THAT ALL PATIENTS/CAREGIVERS RECEIVE THE HANDOUT BELOW:**

**For Regencov (casiri/imde) :** <https://www.fda.gov/media/145612/download>

**For sotrovimab :** <https://www.fda.gov/media/149533/download>

**For bamla/ete:** <http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-patient.pdf>

## **SUPPLIES NEEDED:**

*List of suggested supplies (not exhaustive)*

### **PPE**

- Gloves
- Gowns
- Eye and face protection (e.g. goggles, safety glasses, face shields)
- NIOSH-certified, disposable N95 filter facepiece respirators or better

### **Administration supplies**

#### **IV**

- Infusion chairs –recommended only
- Intravenous administration–IV pole
  - IV administration sets: PVC infusion set with/without DEHP containing 0.2or 0.22 micron polyethersulfone (PES) in-line filter
  - IV and catheters
  - 3mL saline syringes
- Appropriately sized syringes
- Alcohol wipes
- 2x2 gauze pads
- Adhesive bandages
- Tegaderm bio-occlusive dressing
- Absorbent underpads (blue pads)
- Extension set tubing
- Needles –stainless steel 18ga
- Sharps containers
- Transpose tape
- Transilluminator (vein finder, if needed)

#### **Subcutaneous administration**

- Appropriately sized needles for preparation and administration
- Adhesive bandages

#### **General supplies**

- Infusion or allergy Reaction Kit including epi-pen
- Vital signs equipment
- Crash cart or Emergency Medical Management Equipment
- Privacy screens (if applicable)
- Biohazard disposal bag
- Disposable disinfecting wipes
- Thermometer probe covers (if required)
- 70% alcohol wipes
- Paper towels
- Trash bins and liners