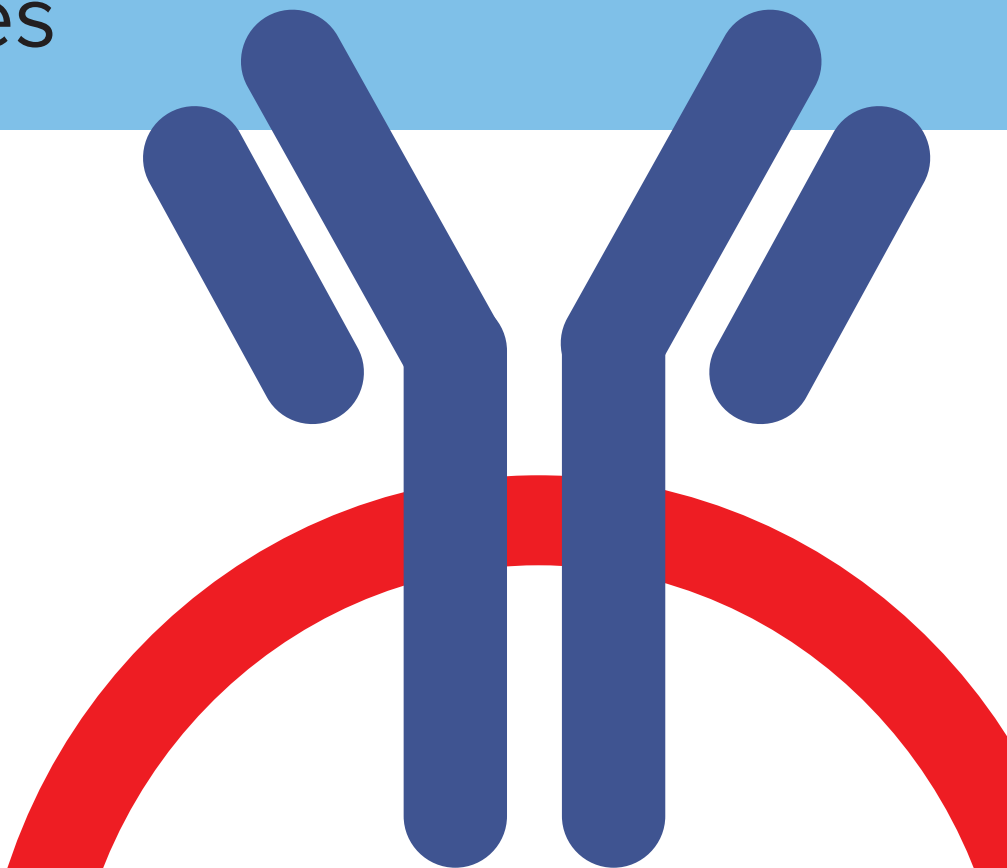
Ohio | Department of Aging
Department of Health

Playbook for Monoclonal Antibody Treatment for COVID-19 Patients in Long-Term Care Facilities

DECEMBER 2021



Playbook for Monoclonal Antibody Treatment (mAb) for COVID-19 Patients in Long-Term Care Facilities

TABLE OF CONTENTS

Ohio | Department of Aging
Department of Health

Updated 12/9/21

About Monoclonal Antibodies for the Treatment of COVID-19

Monoclonal antibodies (mAb) are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. U.S. Food and Drug Administration issued an emergency use authorization (EUA) for monoclonal antibodies that are specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.

The Ohio Department of Health (ODH) is the point of contact for all pharmacies seeking distribution of monoclonal antibody therapies in the State of Ohio. The Ohio Department of Aging (ODA) is assisting ODH to connect long-term care (LTC) pharmacies serving congregate care settings, such as nursing homes and assisted living facilities, with the mAb products they need for their residents.

This booklet was developed by ODA as a supplemental resource for LTC facilities so they may connect older Ohioans in need with mAb therapies available in Ohio. These therapies are medical treatments ordered and administered by licensed healthcare providers. While booklet contents have undergone clinical review at ODA and ODH, healthcare providers should always use their professional discretion for each patient and their unique scenario.

The focus on REGEN-COV, was intentional, as it was more readily available, was stocked by LTC Pharmacies, and was the first to provide for subcutaneous administration, but the principles in this Playbook apply equally to all available products.

This is a living document and will be revised and updated as products and therapy options expand and evolve.

Ohio | Department of Aging
Department of Health

Updated 12/9/21

My Observation of the Benefits of Utilizing mAb for COVID-19

Todd L. Sobol, MD, CMD, Medical Director, Regional Rapid Response Assistance Program

It was early February 2020 when I first heard of an illness that was ravaging the frail residents at a nursing facility in Kirkland, Washington.

After listening to a colleague who was familiar with the facility's situation, I realized both the fear and frustration in his voice. He described an invisible illness that was spreading rapidly among residents and staff. The outbreak was somehow causing an aggressive grave illness resulting in multiple deaths. How do you treat what you do not understand?

It soon became clear that this illness was coming our way. But how do you prepare for a surge of illness of unknown magnitude and poorly defined characteristics?

The usual and customary determinants of best practice did not exist. Well documented case presentations and time-consuming peer reviewed studies did not exist. Communication with colleagues on a local, state, national and international level through frequent emails, calls and meetings via WebEx, Zoom and Teams seemed to be the way to share in the development and understanding to the disease process. The hope was to quickly develop a treatment protocol with some degree of successful outcomes.

As the surge came closer and closer, the same sense of fear and frustration began to seize those tasked with caring for frail residents. Walls could not be built high enough to keep out the storm surge that was on the horizon. With little effective treatment, we did our best to manage symptoms as illness and deaths mounted.

Hope of an effective early treatment began to emerge as mAb treatment results began to enter the discussion. Personally, I had limited experience with mAb treatments other than in treating select autoimmune diseases and cancers. These were generally prescribed by specialists including Rheumatologists or Oncologists. The thought of lab scientists building artificial antibodies that could help the body fight COVID-19 seemed like an idealistic goal: design a drug that works fast to prevent worsening of symptoms in the highest risk patients.

Communication with colleagues was again the key to gaining an understanding. Since trials of Eli Lilly's Regeneron were being conducted in nearby Indiana nursing facilities, I was able to talk with colleagues who observed the impressive initial results firsthand. There was reason for optimism that mAb treatment could be a significant weapon in our battle to fight the effects of COVID-19.

In early November 2020 the United States Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of Bamlanivimab for the treatment of mild-to-moderate COVID-19. We now had an effective treatment option for those at high risk for progressing to severe COVID-19 infection and requiring hospitalization. There were hurdles to overcome in providing this form of IV treatment to patients in long-term care, assisted living and congregate care settings. The priorities included: education of providers and facilities, early detection of eligible patients, identifying sources to obtain the preparation, developing protocols for IV administration and monitoring outcomes.

My Observation of the Benefits of Utilizing mAb Treatment for COVID-19

Throughout the pandemic, providers have been challenged to sort through a confusing barrage of reports of the next breakthrough in treatment. Many were becoming fatigued after trying the latest of multiple treatment protocols with theoretical value without significant proven results. How is it possible to provide IV infusions to patients at the bedside within quarantined and already stressed facilities with low staff availability?

To overcome this understandable resistance, pilot programs were established at multiple centers. Among the larger pilots, Ohio was fortunate to have two pilot programs performed through Coram® CVS Specialty® Infusion Services in the Cleveland region and The Ohio State University pilot in the Columbus area. Encouraging providers and facilities to identify COVID-19 positive patients early and enroll them into the studies was challenging. However, those who participated quickly noted the ease of navigating the process, lack of potential side effects and most importantly improvement in patient outcomes. Providing additional assistance with the infusion process was a key component.

By mid-December, the United States Department of Health and Human Services implemented a new federal allocation program called the Special Projects for Equitable and Efficient Distribution (SPEED). The goal of SPEED was to assist states and territories with identifying and allocating mAbs to non-hospital facilities that serve priority populations, including nursing homes and federally qualified health centers (FQHCs). This program was an addition to the state-based mAb allocation system. Like all medications, there are benefits and risks, so mAb treatments are rightly only available through the direction of licensed healthcare providers.

Studies have now been published that confirm what we have been noting at the bedside. mAb treatment accelerates the natural decline in viral load leading to significant reduction in patient COVID-19 related morbidity, need for hospitalization and mortality. This information combined with a low occurrence of side effects has been driving increased utilization of this treatment option.

Todd L. Sobol, MD, CMD
Medical Director
Regional Rapid Response Assistance Program

INDICATIONS

Post-Exposure Prophylaxis

REGEN-COV is authorized in adult and adolescent individuals (12 years or older) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk* for progression to severe COVID-19, including hospitalization or death, and 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 Centers for Disease Control and Prevention (CDC)**, **OR**
- Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)

The CDC defines close contact as someone who has been within **six feet of an infected person (laboratory-confirmed or a **clinically compatible illness**) for a cumulative total of 15 minutes or more over a 24-hour period.

Treatment for High Risk Individuals* (Symptoms onset < 10 days)

*ANY of the following conditions or medical factors may place adults or adolescent patients (≥ 12 years of age) at higher risk for progression to severe COVID 19 disease:

- Older age (> 65 years of age)
- Obesity or overweight (BMI > 25)
- Pregnancy
- Diabetes mellitus
- Chronic kidney disease
- Immunosuppressive treatment or disease
- Cardiovascular disease or hypertension
- Chronic lung disease
- Sickle cell disease
- Neurodevelopmental disorders
- Having a medical-related technological dependence (tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))

Please refer to your Pharmacy Policy and Procedure for IV Infusions and keep in mind:

- Stability is 36 hours refrigerated.
- Medication needs to warm to room temperature for 20 minutes before administration (do not use warm water or a heating device to bring to temp).
- Do not shake the bag; invert 10 times to mix.
- Prime the infusion set.
- Administer the entire infusion solution in the bag via pump or gravity through an intravenous line containing a sterile, in-line or add-on 0.2-micron polyethersulfone (PES) filter. Due to potential overfill of prefilled saline bags, the entire infusion solution in the bag should be administered to avoid under-dosage.
- The prepared infusion solution should not be administered simultaneously with any other medication.
- After infusion is complete, flush the tubing with either 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP to ensure delivery of the required dose.
- Clinically monitor patients during administration and observe patients for at least 1 hour after infusion is complete.

Contraindications to mAb Infusion Treatment Not authorized for use in the following patients:

- Individuals who are hospitalized due to COVID-19 **OR**
- Individuals who are requiring oxygen due to COVID-19 **OR**
- Individuals who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related co-morbidity.
- Monoclonal antibodies, such as REGEN-COV, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.
- Individuals who do not meet the minimum weight requirement of 40kg/88lb.

mAb SUBCUTANEOUS ROUTE

The subcutaneous route is now authorized by the FDA for REGEN-COV. For treatment, intravenous infusion is recommended. Subcutaneous route of administration is an alternative route when intravenous infusion is not feasible and would lead to a delay in treatment. For post-exposure prophylaxis, either subcutaneous injection or intravenous infusion can be used.

- Remove from refrigerator and allow 20 minutes to come to room temperature. Do not expose to direct heat or shake the vial.
- Inspect vials, should be clear to slightly opalescent, colorless to pale yellow.
- Obtain 3mL or 5mL polypropylene Luer Lock syringes with luer connection and 21-gauge 1½ inch transfer needles. For four (4) 2.5mL injections you will need four syringes.
- Withdraw the appropriate amount of solution into each. Prepare all syringes at the same time.
- Replace the 21-gauge transfer needle with a 25-gauge or 27-gauge needle for subcutaneous injection.
- Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.
- When administering the subcutaneous injections, it is recommended that providers 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.
- Clinically monitor patients after injections and observe patients for at least one hour. A final set of vital signs should always be obtained. When vital signs are normal, repeat in 30 minutes. If vitals are, or become abnormal, frequency should be at least every 15 minutes until they return to normal or additional medical intervention is initiated.
- This product is preservative free and must be administered immediately. If immediate administration is not possible, store the prepared syringes in the refrigerator between 36-46° F for no more than 4 hours, and then allow the syringes to equilibrate to room temperature for approximately 20 minutes.

IMPLEMENTATION | ORDERING

STEP 1

- Get order for treatment from the resident's primary care provider (PCP) or the medical director of the facility.
- Use your pharmacy's order form or the sample included with this booklet.

NOTE

mAb is not a substitution for COVID-19 vaccination.

COVID-19 vaccination (primary series and/or boosters) must be delayed for 3 months after administration of mAb.

IMPLEMENTATION | SITE PREP

STEP 2

- Prepare your facility to participate in mAb administration for COVID-19.
- Healthcare providers can only administer monoclonal antibodies for COVID-19 in settings where providers have immediate access to medications to treat a potential severe infusion reaction (such as anaphylaxis) and the ability to activate the emergency medical system (EMS), as necessary.
- Develop your process for patient screening. Please see Indications on page 4.
- Develop a process to gain patient consent for treatment as indicated by local and state requirements. (See Resource Section)
- Develop appropriate isolation and infection control procedures.
- Ensure your contracted pharmacy can access the mAb product of choice.
- Establish a process for reimbursement for administration costs. (See Resource Section)

IMPLEMENTATION | ADMINISTERING

STEP 3

- Give patients official fact sheet with information about the specific treatment given. (See Resource Section)
- Prepare for the administration process.
- Refer to facility's pharmacy policy and procedure manual for infusion and subcutaneous injection protocols.
- Monitor patients for one hour post-administration for potential side effects.
- Report side effects to FDA MedWatch at **www.fda.gov/medwatch** or call **1-800-FDA-1088** or call **1-844-734-6643**.

IMPLEMENTATION | REPORTING UTILIZATION

STEP 4

- Long-term care facilities report utilization through the National Healthcare Safety Network (NHSN), and instructions are available from the CDC.
  - https://www.cdc.gov/nhsn/ltc/covid19/index.html

NURSING CONSIDERATIONS

CONSIDERATION FOR ADMINISTERING

- Obtain order for mAb.
- Obtain order for the following PRN medications or confirm presence in facility starter kit:
  - Epinephrine, Methylprednisolone Inj, Albuterol Neb or MDI, Diphenhydramine PO/Inj, Famotidine Inj.
- Review FDA fact sheet with resident/POA.
- Verify that resident/POA understands that this medication is not approved to treat COVID-19 infection, but is being used under Emergency Use Authorization (EUA).
- Subcutaneous administration of Regen-Cov is also authorized.
  - Must use four 2.5 mL syringes prepared as per Regeneron protocol and injected into four different injection sites around the thigh, back of upper arm or abdomen at least 2 inches away from the naval. Injections around the waistline are to be avoided.
- IV nursing time is a minimum of 1 hour 20 minutes (20 minutes to infuse and observation one hour post infusion).
  - A 0.2 micron PES filter is required.
  - Casirivimab & Imdevimab – infusion rate is 180-310 mL/hr depending on concentration.
- If a nurse observes signs/symptoms of infusion related reaction, STOP infusion and provide 50 mg diphenhydramine, Albuterol neb treatment and 125 mg Medrol IVP one time.
  - Symptoms include: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.

CONSIDERATION FOR EQUIPMENT

- PPE equipment: N95 mask, face shield/eyewear, gloves, gown
- Monitoring equipment, (dedicated for 2-hour duration): thermometer, BP cuff, stethoscope, pulse oximeter
- Bleach disinfectant wipes for bedside table or prep area
- Disposable paper or plastic surface barrier
- Gloves
- Hand sanitizer
- IV Pole
- IV infusion pump, not mandatory, can use Dial-A-Flow (**Watch Video: https://www.youtube.com/watch?v=-Jb6Fjw1n8Lc**) (John's Hopkins)
- Crash cart, equipment is checked and in working order
- Sharps disposal container
- Alcohol wipes for cleaning catheter port/hub and skin injection sites
- Surgical tape
- Transparent film dressing, (i.e.Tegaderm)
- Skin disinfectant wipes
- Tourniquet
- Gauze 4X4's
- Band-Aids

RESOURCES

INFUSION TREATMENT
REG-COV (Casirivimab / Imdevimab)

ORDER FORM

PATIENT NAME _____ **DATE OF BIRTH** _____

ADDRESS _____

PHONE # _____ **ICD-10 DIAGNOSIS: U07.1 - COVID-19**

NOTE: Casirivimab and Imdevimab (Regeneron's Antibody Combination) is NOT indicated for hospitalized patients, patients receiving supplemental oxygen, or patients on home oxygen who are requiring increase amounts of oxygen.

PATIENT RISK FACTORS:

- ☐ Age ≥ 65
- ☐ BMI ≥ 25
- ☐ Immunosuppressed*
- ☐ Chronic Kidney Disease
- ☐ Sickle Cell Disease
- ☐ Diabetes Mellitus
- ☐ Chronic Lung Disease
- ☐ Cardiovascular Disease or HTN
- ☐ Pregnancy
- ☐ Neurodevelopmental Disorders (Ex. Cerebral palsy)
- ☐ Medical-related technological dependence (ex. Tracheostomy, gastrostomy, etc.)
- ☐ For Prophylaxis - had close contact or high risk to a COVID + individual, and are not fully vaccinated or not expected to mount an adequate immune response to complete vaccination.
- ☐ Other medical conditions/risk factors: _____

** Immunosuppressed - patients on immunosuppressive medications or who have immunosuppressive disease (Ex. CLL)*

Patients who have 1 or more of the above risk factors and are within 10 days of symptoms onset will be eligible for Casirivimab and Imdevimab (Regeneron's Antibody Combination) treatment.

SYMPTOM ONSET DATE _____ **SYMPTOMS** _____

RX

IV Casirivimab 600mg and Imdevimab 600mg (Regeneron's Antibody Combination) added to 100mL of 0.9% sodium chloride for total volume of 100mL x 1 dose.

- Infuse over 20 minutes
- Administer using a 0.2- micron filter
- Observe patient for at least 1 hour following administration
- Flush line with normal saline after infusion to ensure complete dose is given

Infusion reaction protocol will be utilized if a patient has an infusion-related or hypersensitivity reaction.

PRE-MEDS (OPTIONAL)

- ☐ Tylenol 650mg po —— **OR** —— ☐ Tylenol 1000mg po
- ☐ Benadryl 25mg po —— **OR** —— ☐ Benadryl 25mg IV
- ☐ Methypredisolone 40mg IV
- ☐ Other _____

Consider premeds for patients with allergic tendencies or who have had allergic reactions to an immunoglobulin product.

OTHER COMMENTS _____

PRESCRIBER _____ **DATE** _____

PRESCRIBER SIGNATURE _____ **PHONE** _____

ADDRESS _____ **FAX** _____

SUBCUTANEOUS INJECTION
REG-COV (Casirivimab / Imdevimab)

ORDER FORM

FACILITY: .....

NAME OF PRESCRIBER: ..... **PHONE FOR PRESCRIBER:** .....

RESIDENT NAME: ..... **RESIDENT DOB:** .....

RESIDENT WEIGHT: ..... **DRUG ALLERGIES:** .....

INDICATIONS:
IF INDICATED FOLLOWING POSITIVE COVID-19 TEST RESULT, LIST DATE OF TEST: .....
OR,
IF INDICATED BASED ON SYMPTOM ONSET OR EXPOSURE FOR PROPHYLACTIC USE LIST DATE OF ONSET OR EXPOSURE: .....

***According to EUA if a patient requires increased oxygen supplementation, they are not a candidate for this treatment.**

***REGEN-COV may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. (Example: Epinephrine, Benadryl, blood pressure cuff)**

PRESCRIBER MUST INDICATE ALL OF THE FOLLOWING REQUIREMENTS HAVE BEEN MET:

- ☐ Patient/caregiver has been given the Fact Sheet for Patients and Parents/Caregivers
- ☐ Patient/caregiver has been informed of alternatives to receiving REGEN-COV™
- ☐ Patient/caregiver has been informed that REGEN-COV™ is an unapproved product that is authorized for use under an Emergency Use Authorization.

FOR SUBCUTANEOUS INJECTION:
Administer Casirivimab and Imdevimab (600 mg of each) using the co-formulated vial or using the individual vials by subcutaneous injection withdraw 2.5 ml of solution into four separate syringes.

Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.

- **Clinically monitor patients after injections and observe patients for at least 1 hour.**
- **Prescribers are strongly urged to review the EUA on the FDA website.**

FAX TO YOUR PROVIDER PHARMACY.

....
PROVIDER'S SIGNATURE **DATE:**

MEDICARE PAYMENT FOR ADMINISTERING MONOCLONAL ANTIBODY (mAb) PRODUCTS

To ensure immediate access during the COVID-19 Public Health Emergency, Medicare covers and pays for these infusions in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). CMS will address potential refinements to payment for administering mAb products to treat COVID-19 through future notice-and-comment rule-making.

This treatment can be captured under IV Medications in Section O on the MDS, which could increase the Nursing CMG for PDPM based skilled residents. This could also increase the CMI for a Medicaid resident, assuming the resident doesn't already have a higher CMG or CMI.

PAYMENT FOR INFUSION

On May 6, 2021, CMS updated the Medicare payment rates for the administration of COVID-19 mAb products. Effective for services furnished on or after May 6, 2021, the new Medicare payment rate for administering COVID-19 mAb products, authorized or approved by the FDA, is approximately $450. This rate applies to all providers and suppliers not paid reasonable cost for furnishing these products. The new rate reflects updated information about the costs involved in administering mAb products for different types of providers and suppliers, and the additional resources necessary to ensure providers administer the products safely and appropriately to COVID-19 positive patients. CMS geographically adjusts the rate based on where you furnish the service.

Medicare also pays for treatment to address major complications:
- As needed and appropriate
- Consistent with existing payment methodologies for the care setting where you provide the treatment

For COVID-19 mAb products administered before May 6, 2021, the Medicare payment rate is approximately $310.

Medicare will establish codes and rates for administering new products as the FDA approves or authorizes each product.

Get the most current list of billing codes, payment allowances, and effective dates for currently authorized mAb products.

PAYMENT FOR PRODUCT

In response to the COVID-19 PHE, the government is initially purchasing the mAb products to treat COVID-19 and making them available for free. Medicare won't pay for the mAb products to treat COVID-19 that providers get for free. If providers begin to purchase mAb products, CMS anticipates setting the payment rate the same way we set the payment rate for COVID-19 vaccines. For example, Medicare will pay 95% of AWP for COVID-19 vaccines provided in the physician office setting, and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines. Because CMS considers mAb products to treat COVID-19 to be COVID-19 vaccines, they aren't eligible for the New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS).

When providers begin to purchase these products, we'll publish a list of payment allowances and effective dates for the products.

There is No Cost for Your Patients

There's no cost sharing for people with Medicare for these mAb products to treat COVID-19:

- No copayment/coinsurance
- No deductible

SOURCE: CMS.GOV Updated 12/9/21

BILLING FOR ADMINISTERING mAb PRODUCTS TO TREAT COVID-19

Health care providers can bill on a single claim for administering mAb products to treat COVID-19, or submit claims on a roster bill.

- The EUAs for mAb products to treat COVID-19 contain specific requirements for administration that are considerably more complex than for other services that use roster billing. CMS expects health care providers to maintain appropriate medical documentation that supports the medical necessity of the service, including:
  - Documentation that supports that the provider met the terms of the EUAs
  - The name of the provider who ordered or decided to administer the infusion, even in cases where providers use roster billing to submit claims for these services

- When the government provides mAb products to treat COVID-19 for free, providers should only bill for the administration. Don't include the mAb product codes on the claim.

- To ensure access during the PHE, Medicare covers and pays for COVID-19 monoclonal antibodies under the COVID-19 vaccine benefit.

- If you're enrolled as a mass immunizer, you may be able to bill Medicare for administering monoclonal antibodies, consistent with the product's EUA and in accordance with state law and scope of practice.

- Mass immunizers may bill using a roster bill or a traditional claim form, such as a CMS-1500 (PDF) or the 837P electronic format. CMS systems will accept roster bills for 1 or more patients that get the same type of shot (or in the case of monoclonal antibodies, same type of infusion) on the same date of service.

- For patients enrolled in a Medicare Advantage Plan in 2020 and 2021, submit claims for mAb products to treat COVID-19 to Original Medicare through your Medicare Administrative Contractor (MAC). Use your patients' Medicare Beneficiary Identifiers (MBI) to bill Original Medicare.
  - Ask your Medicare Advantage patients for their Original Medicare card. All Medicare patients have a red, white, and blue Medicare card with an MBI, including those enrolled in a Medicare Advantage Plan.
  - If your patients don't have their Original Medicare card or don't know their MBI, use the MBI look-up tool in your MAC's secure portal (PDF). You'll need your patients' first names, last names, dates of birth, and SSNs. You can use the MAC's secure portal to look up the MBI for your Medicare patients even if they're enrolled in a Medicare Advantage Plan.
  - For Part A claims, include Condition Code (CC) 78.

SOURCE: CMS.GOV Updated 12/9/21

MEDICARE PAYMENT FOR ADMINISTERING mAb PRODUCTS TO TREAT COVID-19

CODING FOR MONOCLONAL ANTIBODY PRODUCTS TO TREAT COVID-19

CMS identified specific code(s) for each mAb product to treat COVID-19 and specific administration code(s) for Medicare payment:

PRODUCT	EUA EFFECTIVE & REVOCATION DATE(S)	SPECIFIC CODE	ADMINISTRATION CODE
Eli Lilly and Company's Antibody Bamlanivimab (LY-CoV555)	November 10, 2020 - April 16, 2021 Note: On April 16, 2021, the FDA revoked the EUA for Bamlanivimab when administered alone.	**Q0239** **LONG DESCRIPTOR:** injection, Bamlanivimab-xxxx, 700 mg **SHORT DESCRIPTOR:** Bamlanivimab-xxxx	**M0239** **LONG DESCRIPTOR:** Intravenous infusion, Bamlanivimab-xxxx, includes infusion and post administration monitoring **SHORT DESCRIPTOR:** Bamlanivimab-xxxx infusion
Regeneron's Antibody Casirivimab and Imdevimab (REGN-COV2) (ZIP))	November 21, 2020 - TBD	**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:** Casirivi and Imdevi infusion
Eli Lilly and Company's Antibody Bamlanivimab and Etesevimab, (ZIP)	February 9, 2021 - TBD	**Q0245** **LONG DESCRIPTOR:** Injection, Bamlanivimab and Etesevimab, 2100 mg **SHORT DESCRIPTOR:** Bamlanivimab and Etesevima	**M0244** **LONG DESCRIPTOR:** Intravenous infusion, Bamlanivimab and Etesevimab, includes infusion and post administration monitoring **SHORT DESCRIPTOR:** Bamlan and Etesev infusion
Eli Lilly and Company's Antibody Bamlanivimab and Etesevimab, (ZIP)	February 9, 2021 (reissued on February 25, 2021) – TBD NOTE: While the product EUA was issued on February 9, 2021, this administration code is effective May 6, 2021	**Q0245** **LONG DESCRIPTOR:** Injection, Bamlanivimab and Etesevimab, 2100 mg **SHORT DESCRIPTOR:** Bamlanivimab and Etesevima	**M0243** **LONG DESCRIPTOR:** Intravenous infusion, Bamlanivimab and Etesevimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency. **SHORT DESCRIPTOR:** Bamlan and Etesev infus home

GET THE MOST CURRENT LIST OF BILLING CODES, PAYMENT ALLOWANCES, AND EFFECTIVE DATES.

SOURCE: CMS.GOV Updated 12/9/21

INFORMED CONSENT
FOR MONOCLONAL ANTIBODY (mAb) TREATMENT

Patient Name_____ Date of birth_____

I hereby authorize _____ through its physicians, pharmacists, clinical staff, employees and any others who may be selected, to prescribe and administer a medication, also known as a mAb treatment, for the treatment of mild to moderate coronavirus disease 2019 (COVID-19). I understand SARS-CoV-2 is the coronavirus that causes COVID-19 disease and that there is currently no proven treatment for this potentially serious condition.

It has been explained to me that Monoclonal Antibody Infusion treatment has not been approved but has been authorized for emergency use by the United States Food and Drug Administration (FDA) to treat mild to moderate COVID-19.

1. I understand the FDA has issued an Emergency Use Authorization (EUA) (copy included) to allow limited use of these medications for individuals 12 years or older, weighing at least 40kg (88lbs), with positive results of direct SARS-CoV02 viral testing and who may be at high risk for progressing to severe COVID-19 and/or hospitalization.
2. I have been told and understand that I meet the criteria to receive mAb treatment.
3. I have been told and understand that at this time the mAb treatment will be administered as a single IV infusion, or 4 subcutaneous injections within 7-10 days of symptom onset and additional doses may or may not be necessary.
4. The nature, purpose, and material risks and anticipated benefits of this treatment have been discussed with me. I understand that at this time there are no adequate, approved, or available alternative treatments. I understand there are limited clinical data available for drugs used as mAb treatment. I understand not all risks and benefits of these investigational drugs are known at this time and the serious and unexpected adverse events may occur that have not been previously known or reported.
5. I understand there is limited information about the safety and effectiveness of mAb treatment for management of COVID-19. I understand possible side effects include but are not limited to serious hypersensitivity reaction, including anaphylaxis, difficulty breathing, infusion related reaction such as fever, face or throat, angioedema, throat irritation, rash including hives, itching, sweating, muscle aches, dizziness, and shivering. Additional side effects include but are not limited to pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the injection/ infusion site.
6. I understand that individuals who are severely ill with COVID-19 have an increased risk of dying from the infection, regardless of what treatment is used. I understand that currently the experience with mAb treatment is that it may help individuals who have mild to moderate COVID-19 from progressing to severe COVID-19 and becoming hospitalized.
7. I have been given and read or had read to me the Fact Sheet for Patients, Parents and Caregivers/Emergency Use Authorization (EUA) of Monoclonal Antibodies for Coronavirus Disease 2019 (COVID-19).
8. I understand that the known risks and complications, including unforeseen and unknown risks, may occur.
9. I am aware that the practice of medicine is not an exact science. I acknowledge that no guarantee or promise has been made as to the outcome and/or success of this treatment with medications used for mAb treatment.

INFORMED CONSENT FOR mAb TREATMENT (CONTD.)

Monoclonal Infusion Treatment for Pregnant and Breastfeeding Women

I understand that there is limited experience treating pregnant women or breastfeeding mothers with monoclonal antibodies and that if I am pregnant or breastfeeding, my physician recommends I receive monoclonal antibodies because the potential benefits outweigh the risks to me and my baby.

Patient Consent/Verbal Consent

I understand that no guarantees have been made to me regarding the results of this treatment and that it may or may not improve my condition. I have had sufficient opportunity to discuss my condition and treatment with my physician(s) and/or their associate(s), and all of my questions have been answered to my satisfaction. I have been given sufficient information and knowledge upon which to make an informed decision about receiving medications used for mAb treatment. I have read, or had read to me, and understand the entire contents of this form. I hereby voluntarily authorize and consent to receive medications used for mAb treatment.

I have received a copy of this form.

Patient Signature: _____ Date_____ Time _____

If Legal Representative: _____ Date_____ Time _____

Relationship:_____

PHYSICIAN/PROVIDER DECLARATION:

Whether provided in person or verbally, I confirm that this patient or legal representative has received a full explanation about the nature and purpose of mAb treatment, the risks involved in receiving medications used for mAb treatment, and treatment alternatives. The patient (or Legal Representative) confirms that he/she has received answers to all his/her questions, and to the best of my knowledge, I believe the patient, or their legal representative has been adequately informed and has consented.

Physician Signature: _____ Date_____ Time _____

NURSE VERIFICATION:

☐ Verbal informed consent obtained by physician verified in EHR.

Nurse Signature: _____ Date_____ Time _____

FACT SHEET

For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of REGEN-COV™ (Casirivimab and Imdevimab) for Coronavirus Disease 2019 (COVID-19)

You are being given a medicine called REGEN-COV (Casirivimab and Imdevimab) for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV. Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

WHAT ARE THE SYMPTOMS OF COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS REGEN-COV (CASIRIVIMAB AND IMDEVIMAB)?

REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
  - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), or,
  - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications), **AND**
  - have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, **OR**
  - someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 and the post-exposure prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

WHO SHOULD NOT TAKE REGEN-COV?

Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?

Tell your healthcare provider about all of your medical conditions, including if you:
Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (CASIRIVIMAB AND IMDEVIMAB)?

- REGEN-COV consists of two investigational medicines, Casirivimab and Imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**

- **Treatment:** If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
  - If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous.
- **injections.** If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.
- **Post-exposure prevention:** If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
  - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV(CASIRIVIMAB AND IMDEVIMAB)?

Possible side effects of REGEN-COV are:

- **Allergic reactions.** Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.

- **Worsening symptoms after treatment:** You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?

Like REGEN-COV (Casirivimab and Imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA that are used to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?

Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

There is limited experience using REGEN-COV (Casirivimab and Imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (CASIRIVIMAB AND IMDEVIMAB)?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?

- **Ask your health care provider.**
- **Visit www.REGENCOV.com**
- **Visit https://www.covid19treatmentguidelines.nih.gov/**
- **Contact your local or state public health department.**

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made REGEN-COV (Casirivimab and Imdevimab) available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

REGEN-COV has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Reprinted From Regeneron Fact Sheet:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

Updated 12/9/21

Ohio | Department of Aging
Department of Health