

MONOCLONAL ANTIBODY TREATMENTS IN SENIOR CARE ENVIRONMENTS

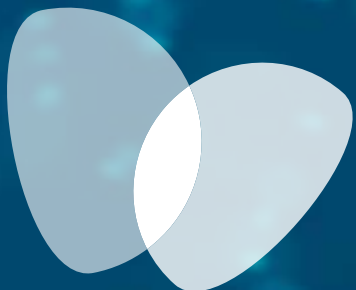
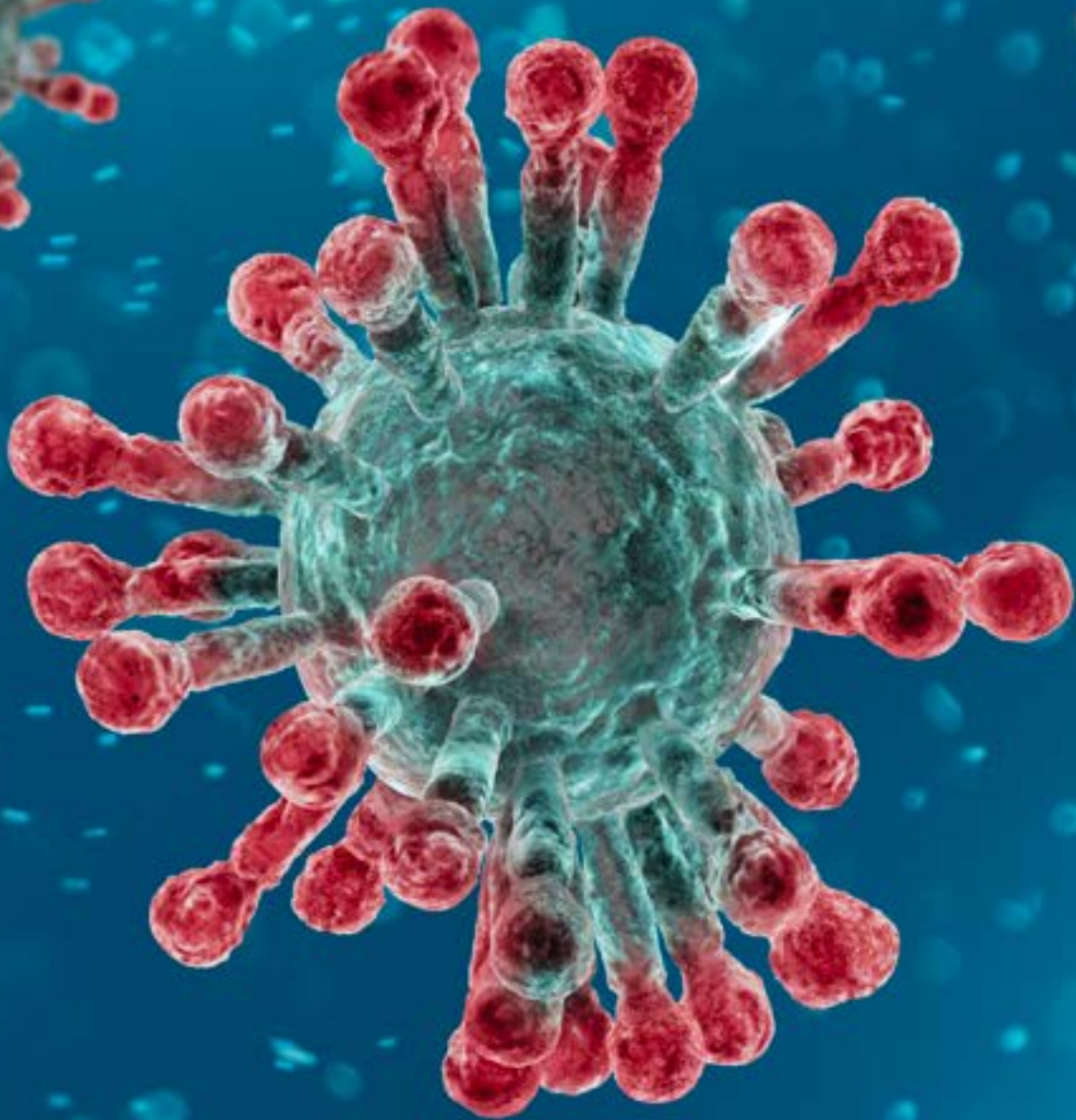
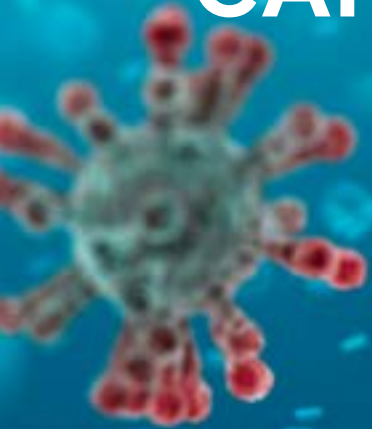


TABLE OF CONTENTS

Introduction	1	Preparation and Administration of casirivimab and imdevimab (Regeneron)	5
Emergency Use Authorizations	1	Monitoring and Reporting of Adverse Reactions	6
Safety	1	Monoclonal Antibody Eligibility Criteria Checklist (Also APPENDIX 3J)	7
Federal Allocation Program/Project SPEED	2	Definitions	7
Allocation Systems by State Jurisdiction	2	Medicare Payment for Monoclonal COVID-19 Infusion	8
ASCP Process for Project SPEED Participation	3	Billing for Monoclonal Antibody COVID-19 Infusion Administration	9
Health and Human Services Guidance	3	Billing Medicare as a Mass Immunizer	9
Monoclonal Antibody Specifications	3		
Preparation and Administration of bamlanivimab (Lilly)	4		

APPENDICES

Appendix 3A - Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction	Appendix 3K - MAb infusion Order Set
Appendix 3B - Casirivimab Imbevimbab EUA Healthcare providers Fact Sheet_12.11.20	Appendix 3L - ASCP PREP Act Liability Memorandum
Appendix 3C - ACIP COVID-19 Vaccine Work Group	Appendix 3M - Medicare Enrollment Application
Appendix 3D - Federal Allocation Program - Description	Appendix 3N - Medicare Enrollment MASS IMMUNIZER
Appendix 3E - State Pharmacy Association Executive Contact List	Appendix 3P - Sample Contract-Part-B-Nursing-Service
Appendix 3F - Bamlanivimab EUA Healthcare Providers Fact Sheet_12.11.20	Appendix 3Q - Data Fields draft 12.7_CDC_Share
Appendix 3G - Casirivimab and Imdevimab EUA Healthcare Providers Fact Sheet_12.11.20	Appendix 3R - Casirivimab + Imdevimab Baseball Cards
Appendix 3H - Medwatch Form	Appendix 3S - Bamlanivimab Baseball Card
Appendix 3J - AMDA Patient Eligibility Checklist	Appendix 3T - Form-MAB-Consent
	Appendix 3U - Bamlanivimab-EUA-Factsheet-Patient
	Appendix 3V - Casirivimab Imbevimbab Treatment-COVID19-EUA-Fact-Sheet-for-Patient



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MONOCLONAL ANTIBODY TREATMENTS IN SENIOR CARE ENVIRONMENTS

Two investigational SARS-CoV-2 neutralizing antibody treatments, bamlanivimab and casirivimab plus imdevimab are now available through Emergency Use Authorization (EUA) from the FDA for use in eligible outpatients with mild to moderate disease who are at high risk for disease progression and/or hospitalization. Both neutralizing antibodies might reduce the rate of hospitalizations and emergency room visits in high risk patients defined as age >65 years and underlying illnesses listed below.¹

At the present time, due to insufficient data the National Institute of Health (NIH) COVID-19 Treatment Guidelines Panel (the Panel) does not recommend either for or against the use of neutralizing antibodies (bamlanivimab or casirivimab plus imdevimab), though preliminary data suggests that outpatients may benefit from receiving anti-SARS-CoV-2 monoclonal antibodies early in the course of infection.²

MONOCLONAL ANTIBODY INFUSIONS ARE NOT A PROPHYLAXIS AGAINST COVID-19.

Residents of skilled nursing facilities (SNFs) are ideal for these novel therapies and long-term care (LTC) pharmacies provide intravenous medications (IV) routinely in SNF environments. In order to best deploy these solutions, state departments of health should engage with LTC pharmacies who can work with their contracted SNFs to obtain orders for the products and convey those orders to the states for allocation from the distributor (AmerisourceBergen). The LTC pharmacies can acquire, safely compound (using clean rooms and aseptic technique), dispense (with patient specific labeling and data tracking) and delivery (appropriately in accordance with required storage and handling specifications) these products with their associated tubing, IV poles, and any required pumps into skilled nursing facilities and other appropriate settings per FDA EUA label.

EMERGENCY USE AUTHORIZATIONS (APPROVED USE):

In patients who are ≥12 years of age and weighing ≥40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization

Anti-SARS-CoV-2 antibody-based therapies may have their greatest likelihood of having an effect in the earliest stages of infection, before the host has mounted an effective immune response. The treatment is a one dose, infused therapy that should be administered as soon as possible after a confirmed positive SARS-CoV-2 test result.

SAFETY:

Infusion-related reactions have been observed and there is potential for severe reactions, including anaphylaxis. Monoclonal antibody treatment may only be administered in settings in which health care providers have immediate access to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS). Post-acute and long-term care settings with access to such expertise and resources may be able to administer monoclonal antibody in their own facilities.

www.fda.gov/media/143603/download

www.fda.gov/media/143892/download

VACCINE CONSIDERATION:

The CDC's Advisory Committee on Immunization Practices has recommended that COVID-19 vaccine should be deferred until 90 days after the administration of monoclonal antibody treatment.³

References:

1. www.covid19treatmentguidelines.nih.gov/therapeutic-management/
2. www.covid19treatmentguidelines.nih.gov/therapeutic-management
3. www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-12/COVID-03-Mbaeyi.pdf

[Return to Table of Contents](#)

FEDERAL ALLOCATION PROGRAM: SPECIAL PROJECTS FOR EQUITABLE AND EFFICIENT DISTRIBUTION (SPEED) - APPENDIX 3D

On Monday, December 14th, the Chief Medical Officer of the Office of the Assistant Secretary for Preparedness and Response at HHS (HHS/ASPR), sent a communication to all State and Territorial Health Officials concerning their oversight of the allocation and distribution of COVID-19 therapeutics administered under Emergency Use Authorization. In support of this responsibility and to assist states and territories with their allocation and distribution efforts, HHS/ASPR is implementing a new federal allocation program called the Special Projects for Equitable and Efficient Distribution (SPEED).

The goal of SPEED is to assist states and territories with identifying and allocating monoclonal antibodies (mAbs) to non-hospital facilities that serve priority populations, including nursing homes and federally qualified health centers (FGHCs). **It should be noted that SPEED is separate and complementary to the state-based mAb allocation system.**

SPEED will be conducted in partnership with national organizations and associations that will assist with educating members (and non-members) and identifying those who are able and willing to administer these infusions. Membership in participating associations is not required for participation as a SPEED facility.

The first two SPEED initiatives will be launched this week and include:

1. Home infusion in nursing homes and assisted living facilities

- a. Description: Home infusion providers in 46 states and the District of Columbia will dispense and provide nursing support for administration of mAbs to residents of nursing homes and assisted living facilities
- b. Patient courses (initial): 560
- c. Launch date: 12/12/20
- d. Partner: National Home Infusion Association

2. Direct allocation to long-term care pharmacies

- e. Description: mAbs will be pre-positioned with long-term care pharmacies for ready deployment when cases occur in nursing homes and assisted living communities served by each pharmacy
- f. Patient courses: TBD
- g. Launch date: Week of 12/14/20
- h. Partners: American Society of Consultant Pharmacists (ASCP); AMDA – The Society for Post-Acute and Long-Term Care Medicine

For LTCFs that do not have the capability of infusing this therapy and are not contracted with a participating LTC pharmacy, they can access mAbs thru the SPEED Home infusion in nursing homes and assisted living facilities. Information about this program can be found on the [NHIA website](#).⁴

Additional SPEED initiatives are being explored for Federally Qualified Health Centers, state/local correctional facilities, dialysis centers, and other settings. Treatment courses allocated through SPEED will be communicated with states for tracking and coordinating purposes.

The information herein this document has been prepared by the American Society of Consultant Pharmacists in consultation with federal agencies to help provide regulatory guidance and should not be taken as legal advice.

ALLOCATION SYSTEMS BY STATE JURISDICTION

The initial distribution of the monoclonal antibody treatments has been allocated through the state jurisdictions. Due to limited state capacity, state jurisdiction have allocated treatments to acute care hospital centers even though the EUAs specifically indicate that these therapies be reserved for non-hospitalized patients. This has led to stockpiling and subsequently led to the development of the SPEED program.

Some states have been deploying treatments to long term care and infusion pharmacies. It is important to understand that these processes and those of SPEED are separate and distinct at this time. Pharmacies that desire to acquire these treatments should pursue relationships with both project SPEED and their local state jurisdiction. At some time downstream, HHS will coordinate with the states to distribute product in collaboration.

APPENDIX 3E is a list of state pharmacy executives that may help with contact to the state jurisdictions.

Reference:

4. www.nhia.org/news/bam-pilot-program/

ASCP PROCESS FOR PROJECT SPEED PARTICIPATION (IN PROCESS)

Pharmacies interested in participating in this federal allocation need to submit information to ASCP (Email Chad Worz cworz@ascp.com) including name of individual location, address, contact person and email address. Request initial allocation which is based on pharmacy size: >5000 SNF beds serviced – 48 doses, 2500 – 5000 SNF beds serviced – 30, <2000 SNF beds serviced – 20. It is critical that doses aren't wasted or that the product isn't placed into environments that cannot manage the administration.

If the location is already an Amerisource Bergen customer, please include your customer ID.

If location is not an Amerisource Bergen customer, please include pharmacy license number for that location. HHS will work to expediate a relationship with Amerisource Bergen Specialty so you may receive the product.

ASCP will keep this information confidential and only be used to communicate to HHS for this program.

HEALTH AND HUMAN SERVICES GUIDANCE

During the COVID-19 public health emergency (PHE), Medicare will cover and pay for these infusions (when furnished consistent with their respective EUAs) the same way it covers and pays for COVID-19 vaccines.

This will allow a broad range of providers and suppliers, including pharmacies, freestanding and hospital-based infusion centers, home health agencies, nursing homes, and entities with whom nursing homes contract for this, to administer these treatments in accordance with the EUA. While Medicare will not pay for the COVID-19 monoclonal antibody products that providers receive for free, Medicare will pay for the infusion. If a change occurs and providers begin to purchase COVID-19 monoclonal antibody products, Medicare anticipates setting the payment rate for the products at 95% of the average wholesale price (AWP), consistent with usual vaccine payment methodologies. Additionally, Medicare anticipates establishing codes and rates for the administration of the products at that time.

In order to facilitate the efficient administration of COVID-19 vaccines to SNF residents, CMS will exercise enforcement discretion with respect to certain statutory provisions. Through the exercise of that discretion, CMS is allowing Medicare-enrolled immunizers including, but not limited to, pharmacies working with the United States, as well as infusion centers, and home health agencies to *bill directly and receive direct reimbursement from the Medicare program for vaccinating Medicare SNF residents.*

Health care providers administering the COVID-19 monoclonal antibody infusions will follow the same enrollment process as those administering the other COVID-19 vaccines. Review [provider enrollment information](#).⁵

Reimbursement (which falls outside of the Part A bundled payment) ideally would be split through Medicare Part B into a pharmacist professional fee for acquisition, compounding, handling and delivery and an administration fee to nursing staff at the SNF. Currently there is an absence of a split payment from CMS, so reimbursement could be provided to the dispensing pharmacy who could in turn reimburse the SNF for administration services based on guidance from CMS.

MONOCLONAL ANTIBODY SPECIFICATIONS

On November 9, 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy, bamlanivimab, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. More information for health care providers and practitioners is [available for review from the manufacturer](#)⁶ (Appendix 3F) and additional materials can be found throughout this packet.

References:

5. www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots

6. pi.jilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf

BAMLANIVIMAB (LILLY)

- The FDA [issued an EUA](#)⁷ to permit the emergency use of bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- Bamlanivimab is not authorized for use in patients who are hospitalized, require oxygen therapy, or 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 comorbidity.

On November 21, 2020, the FDA issued an emergency use authorization (EUA) for casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19. This includes those who are 65 years of age or older or who have certain chronic medical conditions. Casirivimab and imdevimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. More information for health care providers and practitioners is [available for review from the manufacturer](#)⁸ (Appendix 3G) and additional materials can be found throughout this packet.

CASIRIVIMAB AND IMDEVIMAB (REGENERON)

- The FDA [issued an EUA](#)⁹ for this combination for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 (Appendix 3B).
- Not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. There was no evidence of benefit in these patients in randomized, double-blind, placebo-controlled clinical trials conducted with 799 non-hospitalized adults with mild to moderate COVID-19 symptoms.

PREPARATION AND ADMINISTRATION OF BAMLANIVIMAB (LILLY)

Bamlanivimab solution for infusion should be prepared by a qualified healthcare professional using aseptic technique:

- Remove the bamlanivimab vial from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat.
- Inspect bamlanivimab visually for particulate matter and discoloration.
 - Bamlanivimab is a clear to slightly opalescent and colorless to slightly yellow to slightly brown solution.
- Gently invert vial by hand approximately 10 times. Do not shake.
- Dilute bamlanivimab using a 250 mL prefilled 0.9% Sodium Chloride Injection bag for intravenous infusion according to Table 1.
 - Withdraw and discard required volume of 0.9% Sodium Chloride Injection from infusion bag.
 - Withdraw required volume of bamlanivimab from the vial using an appropriately sized syringe.
 - Transfer bamlanivimab to the 0.9% Sodium Chloride Injection infusion bag.
 - Discard any product remaining in the vial.
- Gently invert IV bag by hand approximately 10 times to mix. Do not shake.
- This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted bamlanivimab infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration.
- Gather the recommended materials for infusion:
 - Polyvinylchloride (PVC) infusion set containing a 0.20/0.22 micron in-line polyether sulfone (PES) filter.
- Attach the infusion set to the IV bag.
- Prime the infusion set.
- Administer the infusion solution via pump or gravity over at least 60 minutes.

References:

7. www.fda.gov/media/143603/download
8. pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf
9. www.fda.gov/media/143892/download

Treatment	Dose/Volume of Bamianivimab (# of vials)	Volume of 0.9% Sodium Chloride to Discard from a 250 mL IV Bag	Total Volume for Infusion	Minimum Infusion Rate	Minimum Infusion Time
Bamianivimab	700 mg/20 mL (1 vial)	70 mL	200 mL	200 mL/hr	60 minutes

- Once infusion is complete, flush the infusion line to ensure delivery of the required dose.
- Discard unused product.
- Clinically monitor patients during administration and observe patients for at least 1 hour after infusion is complete.

PREPARATION AND ADMINISTRATION OF CASIRIVIMAB AND IMDEVIMAB (REGENERON)

Casirivimab and imdevimab solution for infusion should be prepared by a qualified healthcare professional using aseptic technique:

- Remove the casirivimab and imdevimab vials 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 vials.
- Inspect casirivimab and imdevimab vials visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded, and fresh solution prepared. The solution for each vial should be clear to slightly opalescent, colorless to pale yellow.
- Obtain an IV infusion bag containing 250 mL of 0.9% Sodium Chloride Injection. Withdraw and discard 20 mL of 0.9% Sodium Chloride Injection from the infusion bag prior to adding casirivimab and imdevimab solutions according to Table 2.
- Withdraw 10 mL of casirivimab and 10 mL of imdevimab from each respective vial using two

separate syringes and dilute together in the infusion bag containing 0.9% Sodium Chloride Injection, see Table 2. Discard any product remaining in the vial.

- Gently invert infusion bag by hand approximately 10 times to mix. Do not shake. This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted casirivimab and imdevimab infusion solution in the refrigerator between 2°C to 8°C (36°F to 46°F) for no more than 36 hours and at room temperature up to 25°C (77°F) for no more than 4 hours, including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 30 minutes prior to administration.

Casirivimab and imdevimab infusion solution should be administered by a qualified healthcare professional using aseptic technique.

- Gather the recommended materials for infusion:
 - Polyvinyl chloride (PVC), Polyethylene (PE)-lined PVC, or Polyurethane (PU) infusion set
 - In-line or add-on 0.2-micron polyether sulfone (PES) filter
- Attach the infusion set to the IV bag.
- Prime the infusion set.
- Administer as an IV infusion via pump or gravity over at least 60 minutes through an intravenous line containing a sterile, in-line or add-on 0.2-micron polyether sulfone (PES) filter.

	Antibody Dose	Volume to Withdraw from Vial	Number of Vials Needed ^b	Volume of 0.9% Sodium Chloride to Discard from a 250 mL Infusion Bag	Total Volume for Infusion	Maximum Infusion Rate	Minimum Infusion Time
Casirivimab and Imdevimab 2,400 mg Dose^a	Casirivimab REGN10933 1,200 mg	10 mL	1 vial of 11.1 mL or 4 vials of 2.5 mL	20 mL	250 mL	250 mL/hr	60 minutes
	Imdevimab REGN10987 1,200 mg	10 mL	1 vial of 11.1 mL or 4 vials of 2.5 mL				

Note: Casirivimab = REGN10933; Imdevimab = REGN10987

a. 1,200 mg of Casirivimab and 1,200 mg of Imdevimab are to be administered together as a single intravenous infusion for a combined 2,400 mg dose.

b. One 11.1 mL vial of on antibody may be prepared with four 2.5 mL vials of the other antibody to create one treatment course.

- e. The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of casirivimab and imdevimab injection with IV solutions and medications other than 0.9% Sodium Chloride Injection is not known.
- f. After infusion is complete, flush with 0.9% Sodium Chloride Injection.
- g. Discard unused product.
- h. Clinically monitor patients during administration and observe patients for at least 1 hour after infusion is complete.

Suggested medications to be available in Nursing home infusion site: E-Box for MAb infusions:	
Medication	Number of doses
Epinephrine 0.3 mg IM	
Methylprednisolone 125mg	
Albuterol neb 2.5 mg INH	
Diphenhydramine 50 mg IV	
Famotidine 20 mg IV	
Albuterol syr 2 mg PO	
Diphenhydramine 25mg PO	

CONSIDERATIONS

- Bamlanivimab storage: Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze, shake, or expose to direct light.
- Casirivimab and imdevimab must be administered together intravenously over 60 minutes.
- Casirivimab and imdevimab vials must be stored in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze, shake, or expose to direct light.
- May only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

MONITORING AND REPORTING OF ADVERSE REACTIONS

- Patients treated with monoclonal antibody treatment should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to CDC guidelines.
- Clinically monitor patients, including vital signs during administration and observe patients for at least 1 hour after infusion is complete.
- There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of monoclonal antibody treatment. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive care.

An FDA [MedWatch Form](#)¹⁰ (Appendix 3H) must be completed to report all medication errors and serious adverse events that occur with treatment of bamlanivimab or casirivimab and imdevimab use and considered to be potentially related to bamlanivimab or casirivimab and imdevimab is mandatory and must be done by the prescribing healthcare provider and/or the provider’s designee. These adverse events must be reported within 7 calendar days from the onset of the event.

***Serious Adverse Events are defined as:**

- Death
- A life-threatening adverse event
- inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- A medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

In addition, please provide a copy of all FDA MedWatch forms to:

Eli Lilly and Company, Global Patient Safety
 Fax: 1-317-277-0853

E-mail: mailindata_gsmtindy@lilly.com

Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events.

or
 Regeneron Pharmaceuticals, Inc
 Fax: 1-888-876-2736

E-mail: medical.information@regeneron.com

Or call Regeneron Pharmaceuticals at 1-844-734-6643 to report adverse events.

Reference:

10. www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting

MONOCLONAL ANTIBODY ELIGIBILITY CRITERIA CHECKLIST (ALSO APPENDIX 3J)

Several monoclonal antibodies have received emergency use authorization from the FDA for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Resident Name:	Room:	Date:
Inclusion Criteria (Must Meet All 3 Criteria)	Yes	No
Mild to moderately symptomatic COVID-19 ¹		
Within 10 days of symptom onset, preferably in the first 3 days		
Positive direct test for SARS-CoV-2 (either A or B) A) If no outbreak present in the building, PCR positive B) If outbreak is present in the building, PCR or antigen positive		
High Risk Criteria for Adults (Must Have 1 of the Following)	Yes	No
Body mass index ≥ 35		
Age ≥ 65		
Chronic kidney disease		
Diabetes		
Immunosuppressive disease or currently receiving immunosuppressive treatment		
≥ 55 years of age AND have: · Cardiovascular disease, OR · Hypertension, OR · Chronic obstructive pulmonary disease/other chronic respiratory disease		
Exclusion Criteria (May Not Have Any of the Following)	Yes	No
Patient is hospitalized or meets hospitalization criteria ²		
Patient requires oxygen due to COVID-19 (Pulse ox $\leq 93\%$ on room air)		
If on chronic oxygen, patient requires an increase in oxygen therapy due to COVID-19		
Patient is on hospice, is hospice eligible, had a palliative care/hospice consult within the prior 6 months, or has a life expectancy less than 6 months (clinician judgement or MDS J1400), inclusions of these residents can be decided on a case by case basis		

DEFINITIONS	
Mild to Moderate Symptoms (1 or more of the following)	Hospitalization Criteria Definition (1 or more of the following)
<ul style="list-style-type: none"> • Fever (99.0 or greater) • New cough • Sore throat • Malaise • Headaches • Muscle pain/aches • Gastrointestinal symptoms • Shortness of breath with exertion • Loss of smell and taste 	<ul style="list-style-type: none"> • RR ≥ 30 • HR ≥ 130 • SBP < 90 despite fluid resuscitation

Infusion-related reactions have been observed and there is potential for severe reactions, including anaphylaxis. Monoclonal antibody treatment may only be administered in settings in which health care providers have immediate access to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS).

Several monoclonal antibodies have received emergency use authorization from the FDA for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Post-acute and long-term care settings with access to such expertise and resources may be able to administer monoclonal antibody in their own facilities.

Administration of monoclonal antibody treatment requires documentation of:

1. Patient has been given FDA Fact sheet for patient.
2. Patient has been informed of alternatives to receiving monoclonal antibody treatment,
3. Patient has been informed that this is an unapproved drug that is authorized for use under the FDA Emergency Use Authorization (EUA)
4. Reporting of adverse events to FDA MedWatch, following the requirements under Emergency Use Authorizations (see last page for details).

COVID-19 OUTPATIENT MONOCLONAL ANTIBODY INFUSION ORDERS - APPENDIX 3K

MEDICARE PAYMENT FOR MONOCLONAL COVID-19 INFUSION

In order to ensure immediate access during the COVID-19 PHE, Medicare will cover and pay for these infusions in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). CMS intends to address potential refinements to payment for COVID-19 monoclonal antibody infusions and their administration through future notice and comment rulemaking.

PAYMENT FOR INFUSION

Initially, for the infusion of bamlanivimab and casirivimab and imdevimab (administered together), the Medicare national average payment rate for the administration will be approximately \$310. This payment rate is based on one hour of infusion and post-administration monitoring in the hospital outpatient setting. At a later date, CMS may use a similar methodology to determine the payment rate for the infusion of additional monoclonal antibody products based on the expected infusion time, consistent with the FDA EUA or FDA approval of such products.

PAYMENT FOR PRODUCT

As noted above, Medicare will not provide payment for the COVID-19 monoclonal antibody products that health care providers receive for free, as will be the case upon the product's initial availability in response to the COVID-19 PHE. If health care providers begin to purchase these monoclonal antibody products, CMS anticipates setting the payment rate in the same way we set the payment rate for COVID-19 vaccines. For example, Medicare will pay 95% of AWP for COVID-19 vaccines furnished in the physician office setting and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines. Because COVID-19 monoclonal antibody products are considered COVID-19 vaccines, they are not eligible for the New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS).¹¹

Should there be additional products that come to market, get the most up to date [list of billing codes, payment allowances and effective dates](#).¹²

People with Medicare pay no cost sharing for these COVID-19 monoclonal antibody infusion therapy products:

- No copayment/coinsurance
- No deductible

References:

11. Note: CMS also anticipates addressing coding and payment rates for administration of monoclonal antibody products through future notice-and-comment rulemaking

12. www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

The ASCP Memorandum on Vaccine Distribution Liability Under Prep Act (Appendix 3L) applies also to the monoclonal antibody treatments.

BILLING FOR MONOCLONAL ANTIBODY COVID-19 INFUSION ADMINISTRATION

Health care providers can bill for the administration of the COVID-19 monoclonal antibody infusion on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill, in accordance with the FDA EUA for each product.

- The EUA for COVID-19 monoclonal antibody treatments contain specific requirements for administration that are considerably more complex than for other services that are billed using roster billing. CMS expects that health care providers will maintain appropriate medical documentation that supports the medical necessity of the service. This includes documentation that supports that the terms of the EUAs are met. The documentation should also include the name of the practitioner who ordered or made the decision to administer the infusion, even in cases where claims for these services are submitted on roster bills.
- When COVID-19 monoclonal antibody doses are provided by the government without charge, providers should only bill for the administration. Health care providers should not include the COVID-19 monoclonal antibody codes on the claim when the product is provided for free.

Health care providers who provide these services to enrollees in a Medicare Advantage Plan should submit claims for monoclonal antibodies to treat COVID-19 that are covered by Part B in accordance with Section 3713 of the CARES Act to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.

CODING FOR MONOCLONAL ANTIBODY COVID-19 INFUSIONS

CMS identified specific code(s) for each COVID-19 monoclonal antibody product and specific administration code(s) for Medicare payment:

[Eli Lilly and Company's Antibody Bamlanivimab](#) (LY-CoV555)¹³, EUA effective November 10, 2020

Q0239:

Long descriptor: Injection, bamlanivimab-xxxx, 700 mg

Short descriptor: bamlanivimab-xxxx

References:

13. www.fda.gov/media/143602/download

14. www.fda.gov/media/143891/download

15. nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions

16. www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf

17. www.cms.gov/files/document/covid-19-mac-webpages-and-hotlines.pdf

M0239:

Long Descriptor: intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring

Short Descriptor: bamlanivimab-xxxx infusion

[Regeneron's Antibody casirivimab & imdevimab](#) (REGN-COV2)¹⁴, EUA effective November 21, 2020

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

BILLING MEDICARE AS A MASS IMMUNIZER

Pharmacies must register as a Mass Immunizer to bill for vaccination administration. Monoclonal antibody treatments are being classified as vaccinations for the purposes of access and reimbursement as well.

Even pharmacies with the ability to bill Medicare Part B must separately register as a mass immunizer.

- Receiving Part B reimbursement includes 2 steps:
 1. Pharmacy must have a National Provider Identification number (NPI). [Click here for more information](#).¹⁵
 2. Apply for a Medicare Part B Provider status: application is CMS Form 855I. [Click here for this form \(link is missing\)](#). (Appendix 3M)
 3. Apply for Mass Immunization Provider Status: application is CMS Form 855B.¹⁶ [Click here for this form](#). (Appendix 3N)

To enroll over the phone as a mass immunizer — call your MAC-specific [enrollment hotline](#)¹⁷ and give your valid Legal Business Name (LBN), National Provider Identifier (NPI), Tax Identification Number (TIN), practice location and state license, if applicable.

ADDITIONAL INFORMATION ON ROSTER BILLING FROM CMS¹⁸

- Medicare will cover the cost monoclonal antibody therapy for COVID-19 treatments, and coverage is extended to beneficiaries in nursing homes at no cost during the public health emergency.¹⁹
- Health care providers can bill for the administration of the COVID-19 monoclonal antibody infusion on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill, in accordance with the FDA EUA for each product. Providers should only bill for the administration and should not include the COVID-19 monoclonal antibody codes on the claim.

PER THERAPY COMPOUNDED AND DELIVERED FOR ADMINISTRATION:

In the absence of a split reimbursement fee designated by CMS for the pharmacy costs and the administration costs, ASCP has proposed the following as a guideline to CMS.

PHARMACIST PROFESSIONAL FEE:

- Consistent with pharmacy costs associated with the following necessary elements:
- Drug Utilization Review (allergies, vaccine specifications, etc.)
- Order entry into system for patients (data collection)
- Product ordering and receiving, with appropriate storage
- Pharmacist aseptic preparation and compounding (clean room)
- Verification/ checking of process
- Labeling of product
- Delivery to facility with appropriate storage of product and supplies (which is often a separate delivery and can be a long distance from the pharmacy)
- Includes appropriate pumps/poles/tubing
- Appropriate billing (Medicare Part B / Nursing facility direct / Commercial or Medicare Part D)

ASCP suggested a total pharmacy cost per therapy of \$147.68 to CMS on 11/24/2020.

Because on the reimbursement structure, either the skilled nursing facility or the pharmacy can bill for the therapy. The product has generally been allocated to pharmacies due to the storage, handling, and compounding of the intravenous (IV) treatment. In skilled nursing environments, nurses are capable of administering and monitoring IV medications. In this described situation, the pharmacy may contract with the nursing facility to reimburse for this administration and monitoring. The rate should be determined fairly between those parties.

APPENDIX 3P is a sample contract between the pharmacy and the LTC facility for reimbursement for the administration and monitoring of the therapy.

Just as with COVID-19 vaccines, the liability for health care providers providing and administering treatments for COVID-19 are protected under the PREP Act provided that they meet the requirements outlines in the EUA. Pharmacies should work with the medical director on an individual basis when dispensing monoclonal antibody treatments to ensure that each facility meets the requirements outlined in the respective EUA.

For skilled nursing facilities and for most assisted living facilities, pharmacies can provide nursing support for the vaccines or can refer those facilities to infusion pharmacies who can provide end-to-end services around the monoclonal antibody treatments.

Provision requirements outside of Skilled Nursing Facilities (ALF, PACE, Community)

For LTCFs that do not have the capability of infusing this therapy and are not contracted with a participating LTC pharmacy, they can access mAbs thru the SPEED Home infusion in nursing homes and assisted living facilities. Information about this program can be found on the [NHIA website](#).²⁰

DATA REPORTING

At this point, data reporting is not a requirement of Project SPEED. This document **APPENDIX 3Q** represents what CDC is considering for reporting in the future. Most of this data is reportable from pharmacy dispensing systems and is documented as part of normal nursing practice in skilled nursing facilities.

References:

18. www.cms.gov/medicare/preventive-services/roster-billing-mass-immunizers

19. www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf

20. www.nhia.org/news/bam-pilot-program/



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