

# Monoclonal Antibody Infusion Center Model (15 Bed)

Based on SARS CoV 2 monoclonal antibody (bamlanivimab, casirivimab and imdevimab) administration needs



## INTRODUCTION

The administration of several therapeutics monoclonal antibodies active against SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), requires intravenous infusion. In order to bolster capacity at the state, tribal, local, and territorial (STLT) levels to deliver therapeutic infusions in an outpatient setting, we have developed the following operational and logistical guidance.

### *Patient Flow, Stations, and Staffing*

The Monoclonal Antibody Infusion Center Model is designed as a point-to-point unidirectional flow model. The model includes a patient intake station, an infusion station, a post-infusion observation station and a patient discharge station.

The length of infusion service for both casirivimab / imdevimab and bamlanivimab should be at least 60 minutes followed by a post-infusion observation period of at least 60 minutes. Refer to FDA Fact Sheet for Healthcare Providers - [bamlanivimab](#), [casirivimab](#) and [imdevimab](#) for more information.

The Monoclonal Antibody Infusion Center Model is designed to be scalable to facility size, community needs, and level of staffing dedicated to operating on a 12-hour workday. Provider-to-patient ratio is based on 15 patients, 1:15 Mid-level Infusion Area and 1:15 Physician Post-Infusion Area, 1:5 RN and/or healthcare worker (e.g., paramedic, emergency medical technician (EMT), patient care technician).

### *Infection Control and Prevention*

In this model, all patients are assumed to be SARS-CoV-2 positive, which speaks to the need for comprehensive [infection-control and prevention practices](#), including [Standard Precautions](#) and [Considerations for Alternate Care Sites](#). Healthcare providers should follow recommended infection prevention and control measures for care of COVID-19 patients. In addition, staff should be trained in recommended IPC measures, including proper donning and doffing of PPE and safe disposal of PPE.

### *Reimbursement*

This document intends to provide a detailed logistical and operational model for a Therapeutic Infusion Center capable of furnishing monoclonal antibodies to treat COVID-19. This document does not establish new facility conditions of participation that are required to bill for services (in certain settings) under federal programs, and does not represent new Medicare/Medicaid payment, coverage or enrollment rules.

## STAFFING NEEDS BY AREA (12 HOURS OPERATIONAL PERIOD)

Entrance or Check-in Station	Infusion Area	Post Infusion Observation	Pharmacy (Optional)	Total Staff Required
1 RN 2 Healthcare workers 1 Runner	1 Mid-Level Provider (ACLS) 2 RN 1 Healthcare workers 1 Environmental Staff	1 Physician 2 RN 1 Healthcare worker 1 Runner 1 Environmental Staff	1 Pharmacist	
<u>Total: 4</u>	<u>Total: 5</u>	<u>Total: 6</u>	<u>Total: 1</u>	<u>Total: 15 (16 including a pharmacist)</u>

# FACILITY LAYOUT

Note: Donning and Doffing areas along with Hot and Cold zones are dependent on facility layout.

## Entrance or Check-in Station

- Staffing: 1 RN and 2 Healthcare workers.
- Critical Functions: At this station, patients and visitors will be greeted, provided a surgical mask, referral-validated, medically evaluated (e.g., history, vitals, known medication allergies, other medical criteria). Both patients and visitors will be masked for the duration of their course of treatment or stay.
- The patient's treatment and monitoring plan and any questions will be discussed.
- Runner: Following initial intake, an identified runner (one of the Healthcare workers) will escort the checked-in patient to the identified infusion station and conduct a hand-off with the IV technician. During the hand-off, the patient will be introduced to the tech and their personal information and treatment course will be confirmed prior to infusion.

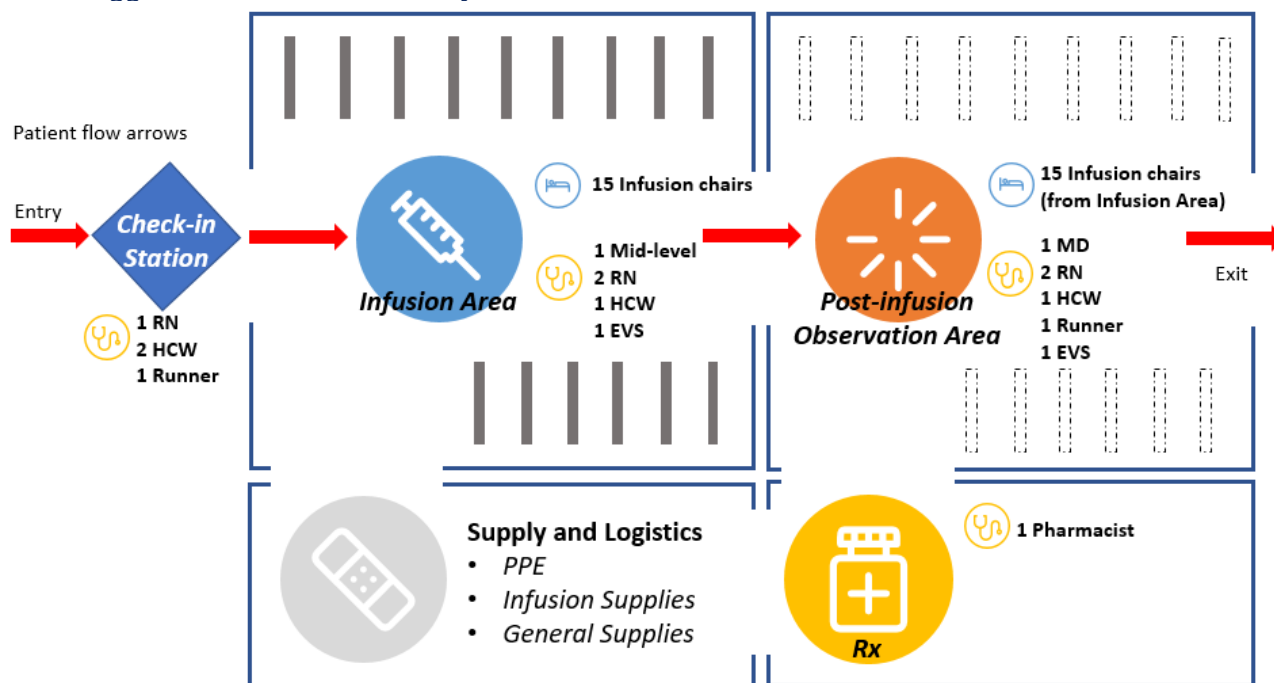
## Infusion Area

- Staffing: 2 RNs, 1 Healthcare worker with IV insertion skills, 1 environmental staff and 1 Mid-level provider (ideally ACLS certified).
- Critical Functions: Identified area for 15 infusion chairs/beds to be placed for infusion services and equipment. At this station, 15 patients would be undergoing infusion.
- The length of infusion service for both [casirivimab / imdevimab](#) and [bamlanivimab](#) should be at least 60 minutes followed by a post infusion observation period of at least 60 minutes. At the time of infusion completion, the patient will be flagged as complete and escorted by the infusing RN to the post-infusion observation area.
- A handoff from infusing RN to post-infusion RN will be made where the patient will be introduced and their personal information and treatment course will again be confirmed.
  - Consider implementing a visual flag system to indicate phase in infusion process - i.e., green is infusing; blue is recovery.
- All beds, stations, and equipment should be [cleaned and disinfected](#) between patients.
- Staff should 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.

## Post-Infusion Observation

- Staffing: 1 Physician, 2 RNs, 1 environmental staff, 1 Healthcare worker (paramedic or second RN).
- Critical Functions: Identified area for 15 infusion chairs/beds to be safely placed for post-infusion observation. At this station, 15 patients would be undergoing direct observation (eyes-on-patient open area) for at least 60 minutes.
- Emergency response equipment required.
- At the conclusion of post-infusion monitoring, patients will have their final medical evaluation for clearance to leave the facility and will receive post-procedure instructions for proper follow-up with a primary care provider.
- Runner: Escort the patient directly to the facility exit.
- All beds, stations, and equipment should be [cleaned and disinfected](#) between patients.

**Figure 1: Suggested Infusion Center Layout**



### Other areas to consider

- **Pharmacy:** Ideally staffed with one pharmacist. Twenty-four hours secure area/room with working sink and sufficient supplies for hand hygiene. Equipment needed: laminar flow hood, syringes, and 250 mL prefilled 0.9% Sodium Chloride Injection (if compounds or mixtures are prepared on-site), refrigerator, temperature-monitoring and alarm system.
- **Laboratory:** A testing area is not recommended within the facility. All patients are considered to be SARS-CoV-2 positive.

## SUPPLIES

- **Handwashing stations-** sinks, soap, and alcohol based hand sanitizer. Cleaning and disinfection supplies.
- **PPE:** gloves, gowns, eye and face protection (e.g., goggles, safety glasses, face shields)
  - NIOSH-approved, disposable fit tested NIOSH-approved N95 filtering facepiece respirators or higher-level respirators.
- **Infusion Supplies:** Infusion chairs, IV pole, IV administration sets – Polyvinyl chloride (PVC) infusion set with/without DEHP containing 0.2 or 0.22 micron polyethersulfone (PES) in-line filter, IV and catheters, 3 mL saline syringes, appropriately sized syringes, alcohol wipes, 2x2 gauze pads, adhesive bandages, dressings, absorbent underpads (blue pads), extension set tubing, needles – stainless steel 18 gauge, sharps containers, tape, transilluminator (vein finder).
- **General Supplies:** infusion reaction kit, vital signs equipment, electronic medical Record (EMR) terminal(s), crash cart or emergency medical management equipment and backboard, refrigerator (optional to store prepared solution onsite), privacy screens, biohazard disposal bag, disposable disinfecting wipes, thermometer probe covers, 70% alcohol wipes, no-touch alcohol dispensers, paper towels, trash bins and liners.

## CRITERIA AND PROTOCOLS

- Develop criteria and protocols based on specific patient, community, and facility considerations.
  - Examples: (1) emergency protocol defined for addressing potential infusion reactions or complications; (2) patient treatment criteria; (3) patient entrance criteria; (4) ambulance staging needed.
  - Patient Flow Patient flow is vital to decrease exposure and limit contact with non-COVID19 patients and staff. Entrance to exit should remain unidirectional patient flow. In general, preexisting healthcare facilities such as health centers, ambulatory care clinics, urgent care centers, etc., have a patient flow and clinical layout already in place. Underutilized areas within facilities could be considered for infusion areas (e.g., Dental Operatories or Physical Therapy areas). Alternate care sites which establish an infusion wing, and freestanding infusion centers should refer to the suggested infusion center layout.

## RESOURCES

- Due to the SARS-CoV-2 positive status of those patients presenting for treatment, proper [infection control and prevention](#) practices and [injection safety](#) are critical. Refer to [CDC guidance documents](#) for additional information.
- Staffing: Twelve-hour operation with at least one provider with current ACLS certification.
  - Physician: 1 (Or mid-level provider if allowed by state law)
  - Mid-level providers (physician assistants, nurse practitioners): 1
  - Healthcare Team:
    - RNs: Minimum of 5
    - Healthcare workers (patient care technicians, EMTs, paramedics): 6
  - Pharmacist: 1 (optional)
  - EVS Staff (2)
  - Total: 15 (16 with a pharmacist)

## PAYMENT FOR MONOCLONAL ANTIBODIES

Many health insurers, including Medicare and Medicaid, will make payments to health care providers that furnish monoclonal antibodies (mAbs) used to treat COVID-19.

Medicare has publicly defined payment policies for COVID-19 mAb products and their intravenous infusion during the Public Health Emergency. Freestanding infusion centers, Alternate Care Sites, and other hospital-based temporary expansion sites may administer mAbs used to treat COVID-19 in accordance with their FDA EUAs. Ensure that hospital conditions of participation and provider-based rules comply with 1135 waivers issued under [Hospital Without Walls](#).

Medicare will not pay for COVID-19 mAb products providers receive for free, namely *bamlanivimab*, and *casirivimab* and *imdevimab* infusion therapies. Medicare will pay for the administration of these treatments. Medicare's national average payment rate is \$310 for infusion of the first two COVID-19 mAb treatments authorized by FDA: *bamlanivimab*, or *casirivimab*, and *imdevimab*. The payment rate is based on one-hour infusion and post-administration monitoring in the hospital outpatient setting. At a later date, CMS may alter the payment rate based on additional information regarding costs providers and suppliers face to administer these products. Refer to [EUA for bamlanivimab](#), [casirivimab and imdevimab](#) for mandatory requirements for administration of these mAb products, which includes patient medical record documentation guidelines.

For mAb products that providers purchase, Medicare's payment rate for is 95% of average wholesale price (AWP). Please refer to future notice-and-comment rulemaking for coding and payment rates for administration of mAb products. For more information on Medicare coverage and payment policies for mAbs used to treat COVID-19, please refer to CMS guidance:

[CMS COVID-19 FAQ on FFS billing \(section BB. Drugs and Vaccines under Part B\)](#)

[Coding and payment information](#)

[Medicare program Instruction for monoclonal antibodies](#)

Medicare's policies may not be adopted by other health insurers. Organizations establishing new programs to infuse mAbs used to treat COVID-19 are encouraged to contact state Medicaid programs and insurers that they have contracts with to determine coverage and payment policies established by that state/insurer.

