Monoclonal Antibody Infusion Center Model (15 Stations)

Based on SARS-CoV-2 monoclonal antibody (bamlanivimab, casirivimab/imdevimab, bamlanivimab/etesevimab) administration needs

INTRODUCTION

The administration of several monoclonal antibodies, active against SARS-CoV-2 (COVID-19), requires intravenous infusion. In order to bolster capacity at the state, tribal, local, and territorial (STLT) levels to deliver infusions in an outpatient setting, we have developed the following operational and logistical guidance for this example model. Facilities and providers should follow state and local regulations/guidelines for each set up and consult the relevant FDA Fact Sheets for Healthcare Providers for additional requirements.

Patient Flow, Stations, and Staffing

This Monoclonal Antibody Infusion Center model is designed as a point-to-point unidirectional flow model. This model includes a patient intake, infusion, and post-infusion observation areas. There are instances where you may see one or more of these areas combined.

The minimum infusion times for the monoclonal antibodies may vary from 16 minutes to 70 minutes (in alignment with product EUA), followed by a post-infusion observation period of at least 60 minutes. Refer to FDA Fact Sheet for Healthcare Providers: bamlanivimab, casirivimab/imdevimab, bamlanivimab/etesevimab for more information.

This Monoclonal Antibody Infusion Center Model is designed to be scalable to facility size, community needs, and level of staffing. The example highlighted is dedicated to operating on a 12-hour workday, with a 15 infusion patient, 15 observation patient capacity.

Infection Control and Prevention

In this model, all patients have received positive SARS-CoV-2 test results, 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.

12 HOUR STAFFING EXAMPLE (15 Infusion /15 Observation site)

Entrance or Check-in	Infusion Area	Post Infusion Observation	Pharmacy (Optional)	Total Staff Required
1 RN / Medical Tech (Basic/ Paramedic) with Triage skills 1 Runner 1 Scribe/Registrar (optional)	1 Physician / Advanced Practioner (onsite or accessible via telemedicine) 2 RN 2 Healthcare workers 1 Environmental Staff (optional)	1 RN 1 Healthcare worker 1 Runner 1 Environmental Staff (optional)	1 Pharmacist (optional)	
Total: 2 (plus 1 optional)	**Total:** 5 (plus 1 optional)	**Total:** 3 (plus 1 optional)	**Total:** 0 (plus 1 optional)	**Total**:10 (plus 4 optional)

FACILITY LAYOUT

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

Entrance or Check-in Station

- Staffing: 1RN / Medical Technician (basic / paramedic) with triage skill set.
- Critical Functions: At this station, patients will be greeted, provided a surgical mask, referral-validated, medically evaluated (e.g., history, vitals, known medication allergies, other medical criteria). Patients will be masked for the duration of their course of treatment or stay. If the site model includes an on-site provider, patients without a referral may have medical intake performed, test results confirmed, and monoclonal therapy ordered.
- Runner: Following initial intake, an identified runner will escort the checked-in patient to the identified infusion station and conduct a hand-off. No visitors will be allowed in the infusion or observation area.

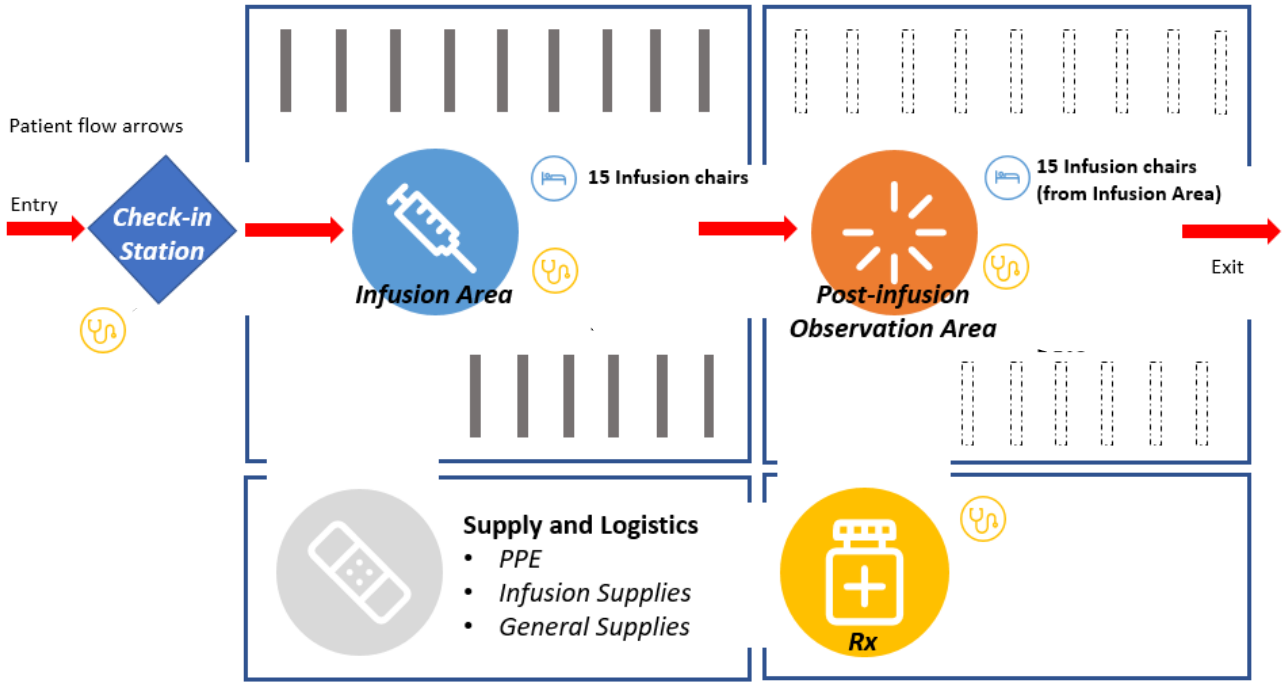
Infusion Area

- Staffing: 2 RNs with IV insertion, preparations and infusion skill set, 2 Healthcare workers, one with IV insertion skills, 1 environmental staff (optional) and 1 Physician /Advanced Practitioner (onsite or available via telemedicine)
- Critical Functions: Identified area with 15 infusion treatments spaces including a chair/cot/bed
- Minimum Infusion times for casirivimab / imdevimab, bamlanivimab and bamlanivimab / etesevimab vary and can range from 16 minutes to 70 minutes depending on the product and the product EUA. All infusions must be followed by an observation period of 60 minutes as identified in the product EUA. Patients may spend their observation period in the same chair/bed/cot space that they were infused in or be relocated to an adjacent area for their observation phase.
- All chairs, beds, cots, 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 RN, 1 environmental staff (optional), 1 Healthcare worker (medical technician)
- Critical Functions: Identified area for 15 post-infusion patients to complete their observation period for 60 minutes, based on the product EUA.
- If a patient's observation phase is in a different space than their infusion, 15 chairs/beds/cots should be safely placed in an open area for direct observation (eyes-on-patient).
- 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.
- 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. (Optimal practice is scheduling of a follow-up in person or telemedicine visit prior to discharge from the infusion site)
- Runner: Escort the patient directly to the facility exit.
- All beds, stations, and equipment should be cleaned and disinfected between patients.

Figure 1: *Example of a15 Patient Infusion Center Layout*



Other areas to consider

- **Pharmacy**: A Pharmacy and or onsite Pharmacist is optional. Per the EUAs for the monoclonal therapeutic antibodies, infusions can be prepared by a qualified healthcare professional using aseptic technique, and do not require a laminar flowhood for preparation. A refrigerator with temperature-monitoring is required for onsite monoclonal antibody product storage
- **Laboratory:** A testing area within the infusion site is not required as all eligible patients are documented confirmed 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:* Patient chairs,beds, cots, IV poles, 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)-optional. Dial a flow (IV gravity flow rate regulator). IV pumps are not required for infusions.
- *General Supplies:* infusion reaction kit, vital signs equipment, electronic medical Record (EMR) terminal(s) or paper forms, refrigerator, 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 if needed.
  - *Patient Flow* Controlled Patient flow to and from the treatment area 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.

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, bamlanivimab / etesevimab andcasirivimab / 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, bamlanivimab / etesevimab, or casirivimab / 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 /imdevimab and bamlanivimab / etesevimab 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.

For information on obtaining monoclonal antibodies for non-hospital sites, refer to the FAQs for non-hospital sites.