# Infusion Units for COVID-19 Antibody Treatment

**OPERATIONS GUIDE**

VERSION 1.0

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SECTION 01

# Abbreviations

# ABBREVIATIONS

- **Ab:** Antibody
- **ACLS:** Advanced cardiovascular life support
- **BP:** Blood pressure
- **BLS:** Basic life support
- **DEHP:** Di(2-ethylhexyl)phthalate
- **DO:** Doctor of Osteopathic Medicine
- **EMS:** Emergency medical services
- **EUA:** Emergency Use Authorization
- **HCP:** Healthcare provider
- **HIPAA:** Health Insurance Portability and Accounting Act
- **HR:** Heart rate
- **IV:** Intravenous
- **MD:** Doctor of Medicine
- **N95:** A U.S. standard that requires masks to be able to filter out at least 95% of very small particles, including droplets containing COVID-19.
- **NP:** Nurse practitioner
- **PA:** Physician assistant
- **PCR:** Polymerase chain reaction
- **PICC:** Peripherally inserted central catheter
- **PPE:** Personal protective equipment
- **PVC:** Polyvinyl chloride
- **RR:** Respiratory rate
- **SAE:** Serious adverse event

SECTION 02

# Introduction

# INTRODUCTION

## Purpose

Eli Lilly and Company is bringing the full force of its scientific and medical expertise to attack the coronavirus pandemic around the world. Recent authorization by regulatory authorities has provided new treatment options for patients with COVID-19. The availability of these new therapeutic treatments requires partnership between pharmaceutical companies and the broader healthcare community to ensure essential access to these medicines. Increasing ambulatory infusion services for patients with COVID-19 is a critical aspect in fighting this pandemic.

This Operations Manual provides recommendations for establishing infusion units to treat patients with COVID-19 in diverse settings. It was developed based on Lilly's experience working with health networks and hospital systems to establish two separate pop-up infusion units.

The recommendations herein are not meant to supplant or supersede any local, state or other applicable requirements. It is your obligation to know those requirements, and to follow them should they conflict with the recommendations herein.

The figure below depicts a high-level process overview for use of therapeutic neutralizing antibodies in patients with COVID-19.

Providing access to new COVID-19 treatments involves a multi-step process, including:


This manual addresses Step 3: Product Administration (Infusion), and includes process steps that represent an example approach to establishing an ambulatory infusion unit with no existing process or infrastructure. This is intended to depict minimum recommendations for operating an infusion unit. These guidelines are not intended to supersede local recommendations and practices.

SECTION 03

# Resources and Staffing

# RESOURCES AND STAFFING

### Recommended Resources

**Table 4.1** lists the roles and staffing recommendations for an ambulatory infusion unit administering therapeutic neutralizing antibodies to patients with COVID-19.

In addition, the infusion unit must have a licensed practitioner (MD/DO/NP/PA) readily available on-site, by phone or by telehealth during medication administration.

Preparation of IV admixture can be conducted at the infusion unit by a trained healthcare provider as determined by state and local requirements. IV admixture should be prepared in a secure area with a working sink available.

**Table 4.1:** Staffing Recommendations *(All individuals should be trained to wear PPE.)*

| Role | Recommendations |
|---|---|
| **Patient intake** | Person with basic administrative skills |
| **Drug infusion preparation** | Healthcare professional trained in IV admixture preparation (e.g., nurse, pharmacist, pharmacy tech) |
| **Infusion: start IV, administer infusion, monitoring** | Healthcare professional trained in:<br>• starting an IV<br>• administering IV infusion<br>• assessing infusion-related reactions<br>• treating infusion-related reactions<br>• vital sign monitoring |
| **Post-infusion observation** | Healthcare professional trained in:<br>• assessing infusion-related reactions<br>• treating infusion-related reactions<br>• vital sign monitoring<br>• providing discharge education for the patient |
| **Patient release** | Person with basic administrative skills |
| **Waste removal and cleaning** | Person trained in COVID-19 cleaning and disinfection |

**Notes:**

- Infusion units should consider having at least one healthcare professional with Advanced Cardiovascular Life Support (ACLS) certification, Basic Life Support (BLS) certification or equivalent.
- At least one healthcare professional should be able to respond to medical emergency (e.g., severe infusion reaction); specific certifications may be required based on state and healthcare facility regulations and policies.
- The same healthcare professional may perform more than one role. Cross-training tasks where possible will provide the greatest flexibility in an infusion unit.
- State or country recommendations may dictate specific qualifications for some roles.

SECTION 04

# Equipment and Supplies

# EQUIPMENT AND SUPPLIES

### Basic Equipment Recommendations

The tables in this section list the basic equipment and supply recommendations for an ambulatory infusion unit to administer therapeutic neutralizing antibodies to patients with COVID-19. Each table covers a single process step and is labeled accordingly.

**Table 5.1**

| Process Step: Patient Intake | | |
|---|---|---|
| **Unit Equipment and Supplies** | **Medical Supplies** | **PPE** |
| Patient instructions and overview<br>Phone<br>Scheduler and list of appointments<br>Office supplies (e.g., pens, stapler, scissors, paper clips, printer, etc.)<br>Clipboard<br>Patient Infusion Flowsheet and Infusion Reaction Forms<br>Check-in table<br>Chair(s) for check-in staff<br>Bleach sanitizing wipes<br>Hand sanitizer<br>Storage containers<br>Hospital grade disinfectant | Wheelchairs | Gloves (all sizes)<br>Face shields or goggles<br>N95 masks for staff<br>Gowns, hair caps and shoe covers |

**Table 5.2**

| Process Step: Drug Preparation (May vary by product) | | |
|---|---|---|
| **Equipment and Supplies** | **Medical Supplies** | **PPE** |
| Locked refrigerator with temperature monitoring<br>Wireless temperature monitor or equivalent<br>Preparation table, chair<br>Sharps containers<br>Drug transport bags (if using mobile pharmacy)<br>Alcohol sanitizing wipes<br>Step-by-step instruction sheet (with images)<br>Storage containers<br>Hospital grade disinfectant | 18 ga needles<br>Appropriately sized syringes<br>250 mL normal saline bags<br>Normal saline bag or syringe for flush<br>Sterile alcohol prep pads | Gloves (all sizes)<br>Face shields or goggles<br>N95 masks for staff (only if the drug is prepared in a COVID-19 area)<br>Gowns, hair caps and shoe covers |

**Table 5.3**

| Process Step: Infusion | | |
|---|---|---|
| **Unit Equipment and Supplies** | **Medical Supplies** | **PPE** |
| Chairs for infusion<br>Chairside table<br>Chairs for staff<br>Supply cart or other storage cabinet<br>Hand sanitizer<br>Hand soap (if sink available)<br>Biohazard trash can<br>Bleach wipes (for cleaning non-electronic equipment)<br>Alcohol wipes (for cleaning electronic equipment)<br>Storage containers<br>Timers for IV stations and observation<br>Hospital grade disinfectant | IV poles<br>IV pumps (or gravity feed)<br>Vital signs monitoring equipment (BP, HR, resp rate, temp, O2 sat)<br>Sterile alcohol prep pads<br>IV catheters<br>IV extension tubing<br>IV caps<br>Tourniquet<br>PVC infusion sets<br>0.20/0.22 µm polyethersulfone (PES) in-line filter<br>Gauze pads<br>Bandages<br>Saline flush syringes to lock IV<br>Bio-occlusive dressing<br>Tape<br>Normal saline bag or syringe for flush<br>Stethoscopes<br>Pulse oximeters | Gloves (all sizes)<br>Face shields or goggles<br>N95 masks for staff<br>Gowns, hair caps and shoe covers |

**Table 5.4**

| Process Step: Observation and Release | | |
|---|---|---|
| **Facility Configuration Equipment and Supplies** | **Medical Supplies** | **PPE** |
| Table for staff<br>Chairs for patients and staff<br>Bleach sanitizing wipes (for cleaning non-electronic equipment)<br>Alcohol sanitizing wipes (for electronic vital sign equipment)<br>Hand sanitizer<br>Timers for IV stations and observation<br>Hospital grade disinfectant | Vital signs monitoring equipment (BP, HR, resp rate, temp, O2 sat)<br>Stethoscopes<br>Pulse oximeters | Gloves (all sizes)<br>Face shields or goggles<br>N95 masks for staff<br>Gowns, hair caps and shoe covers |

### Medical Emergency Supplies

Each infusion unit should have medical emergency supplies and medications (e.g., infusion reaction kit), a qualified healthcare provider and emergency procedures.

It is essential that infusion units have standard operating procedures in place, including instructions for unit staff on the management of emergency events and contacting emergency medical services.

**Table 5.5** lists medical emergency supplies.

**Table 5.5**

| | Minimum Recommendations | Additional Considerations |
|---|---|---|
| **Medications**<br>Supply should be adequate to treat expected number of patients and hypersensitivity reactions | Albuterol inhaler<br>Diphenhydramine injection<br>Epinephrine 0.1 mg/mL (1 mg/10 mL) OR epinephrine auto-injector 0.3 mg<br>Solu-Medrol injection | Adenosine injection<br>Atropine sulfate<br>Chewable ASA<br>Dextrose 50% injection<br>Insta-Glucose<br>Nitroglycerine<br>Ondansetron injection<br>Sodium bicarbonate injection |
| **IV Supplies** | 0.9% sodium chloride flush (10 mL)<br>0.9% sodium chloride bag (500 mL) | IV admin set<br>IV start kit<br>IV catheter<br>Non-DEHP cath/extension set<br>5% dextrose bag |
| **Airway** | Oxygen (nasal cannula/face mask) | Airway equipment (oral airway, suction, face mask, ambu bag) |

SECTION 05

# Facilities

# FACILITIES

### Facility Design Recommendations

Listed below are facility recommendations for an ambulatory infusion unit to administer therapeutic neutralizing antibodies to patients with COVID-19.

- Separation of patients with COVID-19 through scheduling and/or separate physical location (from entry through exit).
- Areas for check-in, infusion and observation of patients with COVID-19.
- Separate restrooms for patients and staff within or adjoining the infusion unit.
- Separate area for infusion unit staff to don PPE equipment prior to entering the infusion unit.
- Clear signage at entrances providing direction for patients to minimize interaction of patients with COVID-19 with staff and other patients.
- Chair configuration allowing space for infusion unit staff to conduct procedures.
- Americans with Disabilities Act (ADA) or country equivalent compliant access (wheelchair accessible).
- Appropriate infusion unit security.
- Infusion units should consider technology infrastructure to meet operational needs. Basic considerations may include WiFi access, printers, scanners, fax capability and phone service.
- Consideration for whether management of the facility will be impacted by the number of air exchanges per hour. For example, “hospital grade” is considered six air exchanges per hour.
- Units should establish when they would consider the area clean enough to enter without N95 or equivalent PPE.
- If at all possible, ensure the infusion unit has a floor surface that can be mopped rather than carpet.

### General Cleaning and Sanitization Guidance

Listed below are cleaning and sanitization recommendations:

- All surfaces in contact with patients with COVID-19 must be sanitized between uses, this includes chairs for infusion and equipment (blood pressure cuff, pulse oximeter, stethoscopes, etc.)
- For COVID-19 disinfectants, surface types and contact time required, please visit: **https://cfpub.epa.gov/giwiz/disinfectants/index.cfm**
- For additional guidance on disinfecting, please visit: **www.epa.gov/sites/production/files/2020-04/documents/316485-b_reopeningamerica_combo_placard_infographic_4.19_6pm.pdf**
- Arrange routine housekeeping and laundry services.

SECTION 06

# Process

# PROCESS

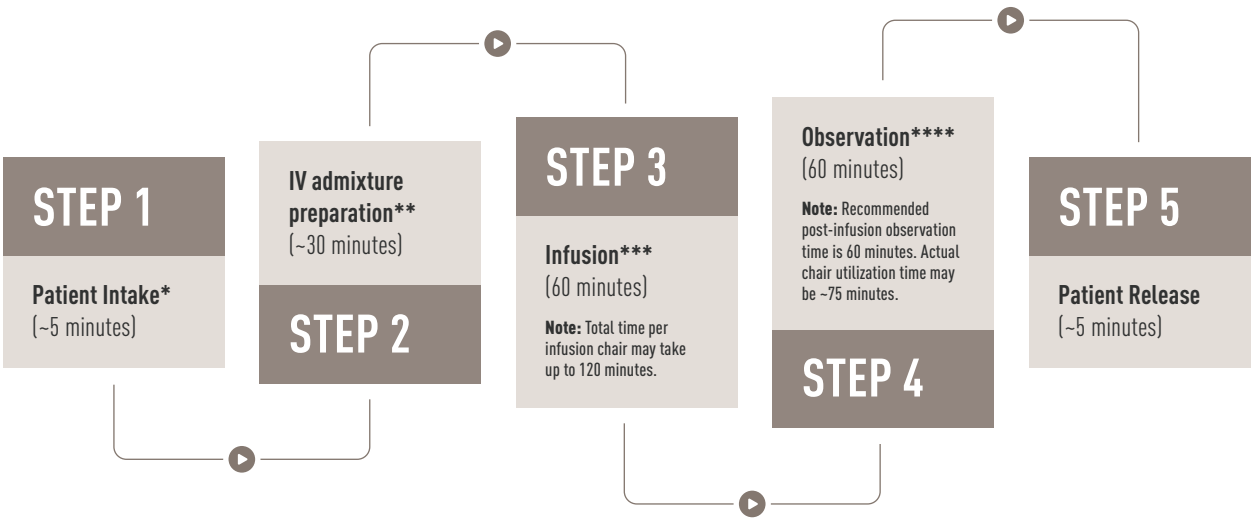
Process steps are examples only. The process overview for the administration of therapeutic neutralizing antibodies represents an example approach to establish an ambulatory infusion unit with no existing process or infrastructure. The process is intended to provide recommendations for operating an infusion unit. These recommendations are not intended to supersede local requirements and practices.

### High-Level Process Overview

The high-level process overview in this section is divided into five main steps, with estimated time periods assigned to each step. Further details about each step are also provided later in this section.

For the entire process outlined below, infusion units should allow approximately three hours per patient. Total time may be shortened if IV admixture is prepared in advance of patient arrival (see note below about Step 2: IV Admixture Preparation).

Total time and time of each step may vary based on product-specific instructions and specific infusion unit operations.




***Prior to administration, a patient should have:**

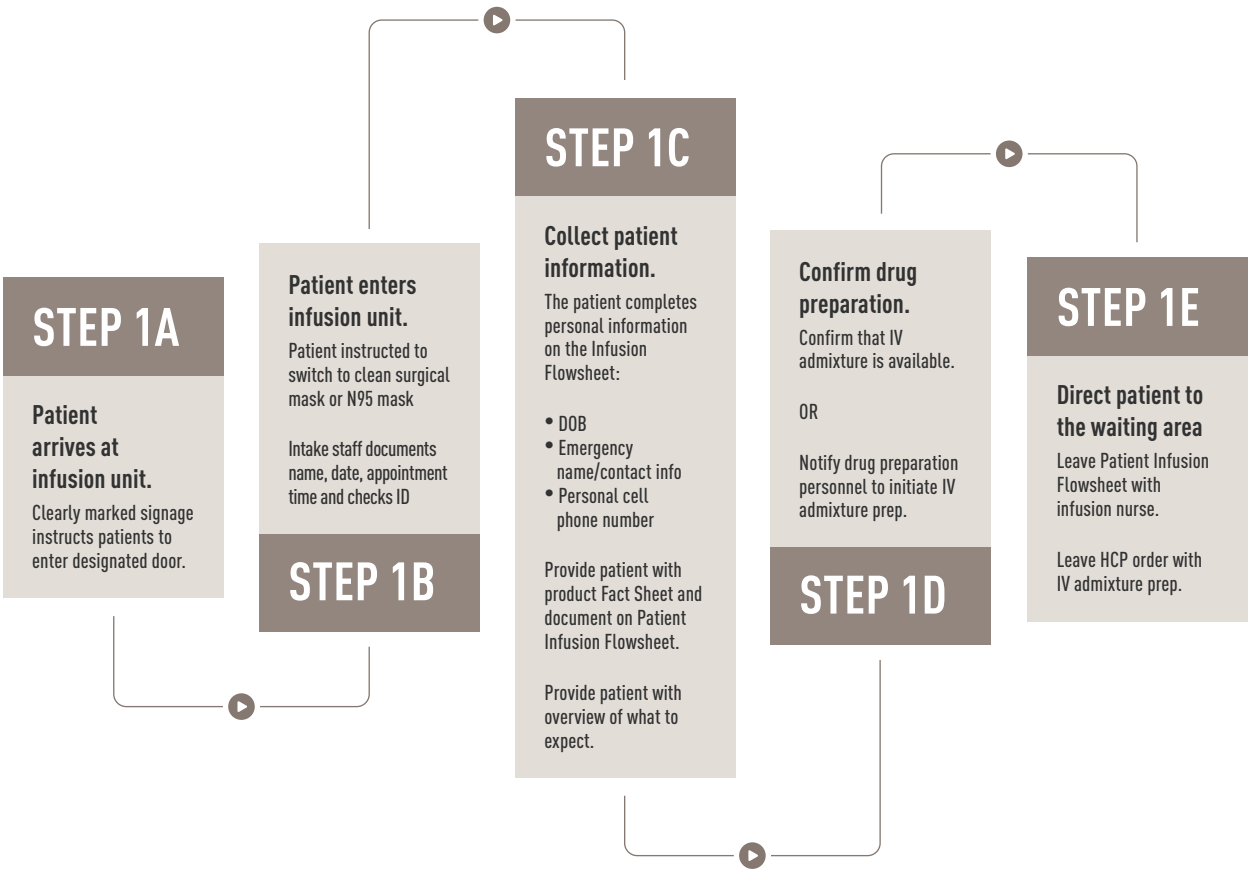
- Been referred by HCP and have a prescribing HCP order per EUA guidelines.
- Registered in advance (e.g., online, phone call).
- Been provided directions and instructions at time of appointment or registration.

****Step 2: IV Admixture Preparation can occur prior to, in parallel with or after Step 1: Patient Intake.**

*****Step 3: Example used a recommended infusion time of 60 minutes. Consult EUA for actual recommended infusion time.**

******Step 4: Post-infusion observation times may vary up to 120 minutes or more.**

# STEP 1: PATIENT INTAKE

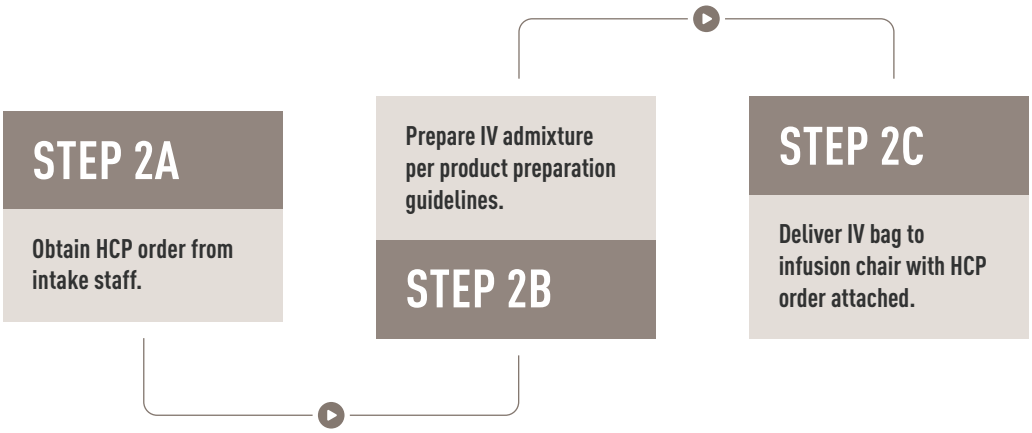



**Additional considerations for Step 1: Patient Intake:**

- If space constraints prevent use of a check-in or waiting area, patients may be asked to wait in their car and call the infusion unit upon arrival. In such cases, patient intake activities can be conducted via phone.
- Have copies of the Fact Sheet for each product to provide to patients.
- Signage outside of the infusion unit should restrict entry for all individuals other than the patient being treated. Exceptions may be made in situations where the patient is a minor.

# STEP 2: IV ADMIXTURE PREPARATION

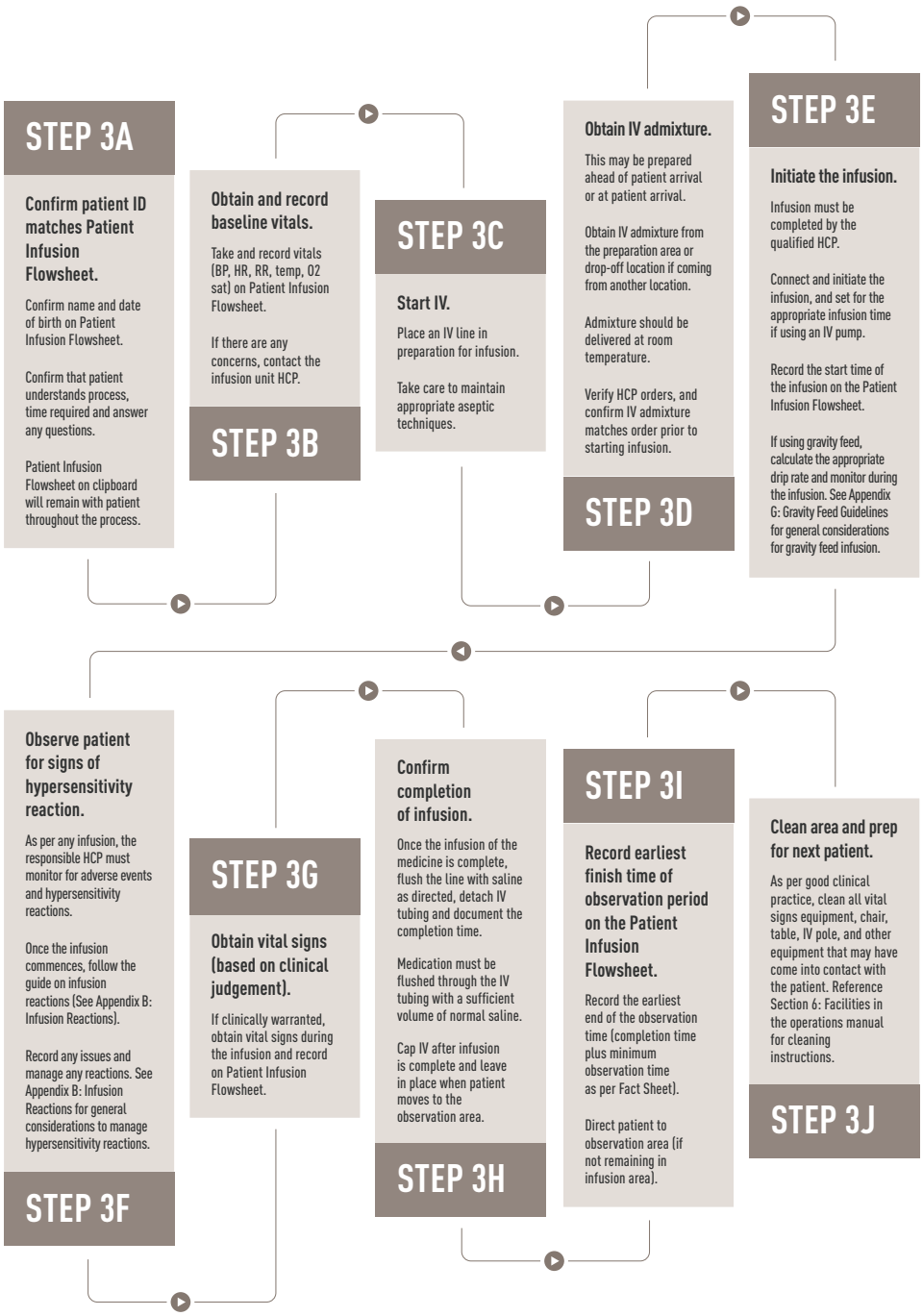
Step 2: IV Admixture Preparation can occur prior to, in parallel with or after Step 1: Patient Intake.




**Additional considerations for Step 2: IV Admixture Preparation:**

- Infusion units must refer to product-specific recommendations to ensure appropriate product conditions are maintained during storage, preparation and transportation.
- Maintain drug accountability log to link drug lot number to patient.
- Depending on infusion unit practice and considering product preparation and storage recommendations, IV admixture may be prepared in advance of patient arrival at the infusion unit.
- IV admixture should be labeled with patient's name and DOB, drug name and dose, diluent type and volume, date and time of preparation, and recommended infusion time, per healthcare provider order.
- Consider process for managing inventory of product from each manufacturer with that of the appointment demand to ensure availability of the prescribed medicines before confirming appointments.

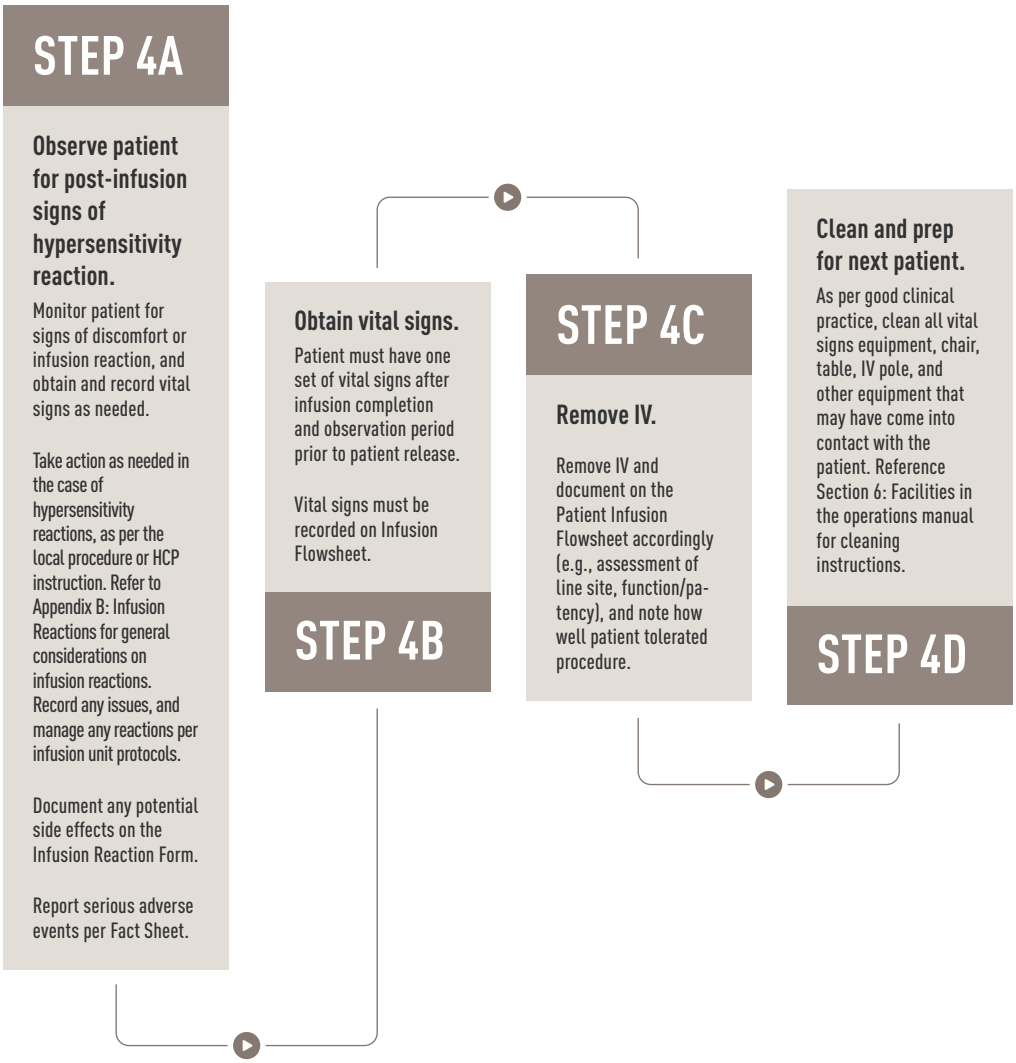
# STEP 3: INFUSION




**Additional considerations for Step 3: Infusion:**

- Recommend adding the lot number of the product to the Patient Infusion Flowsheet.
- For patients with a central catheter (PICC line), defer to the local practice. See **Appendix C: Central Line Access and Care** for additional information.
- After the entire infusion volume has been administered, flush the tubing with a sufficient volume of saline to clear residual volume from tubing and ensure the patient receives the entire dose.

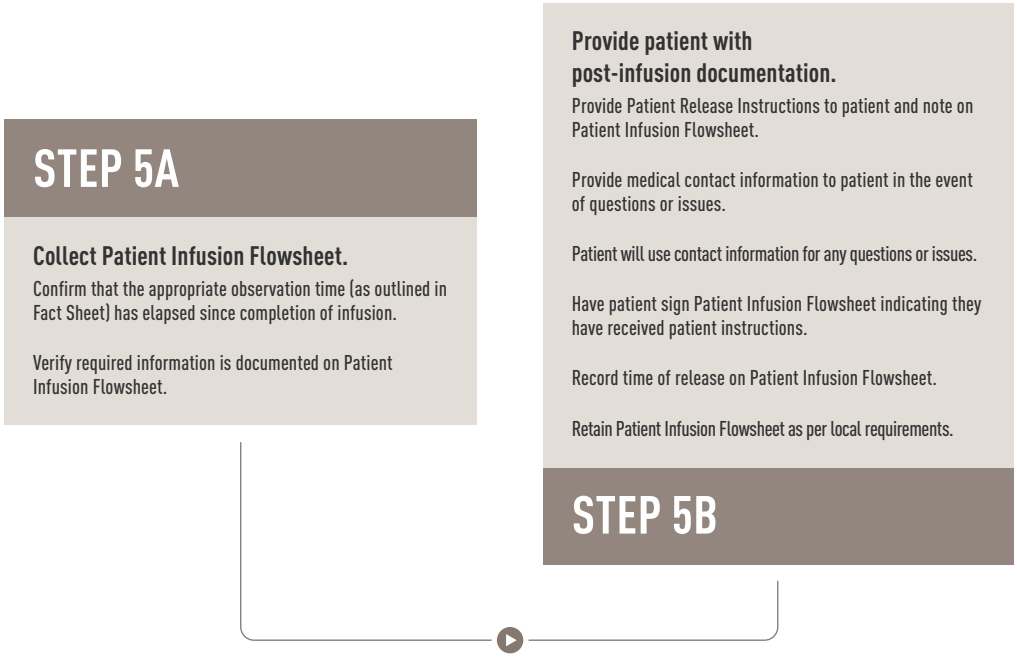
# STEP 4: POST-INFUSION OBSERVATION




**Additional considerations for Step 4: Post-infusion Observation:**

- The patient may remain in infusion chair for observation or be directed to the post-infusion observation area.

# STEP 5: PATIENT RELEASE




**Additional considerations for Step 5: Patient Release:**

- Implement procedure on how to manage patient documentation after the patient is released, including collection, handling, storage and retrieval of contaminated paper.
- The recommended observation time is at least 60 minutes, or as per the Fact Sheet, or based on healthcare provider judgement and patient profile.

# ADDITIONAL CONSIDERATIONS FOR INFUSION UNITS

- **Documentation processes may vary:** Documentation and maintenance of patient records may differ according to practices at the unit or institution. The process in this document includes use of paper forms for drug accountability, patient intake and documenting infusion details. A facility can use existing equivalent processes for documentation (e.g., electronic). Documentation must be maintained in a HIPAA compliant manner for the US or meet appropriate standards for each country.
- **Patient education:** This will occur at the point of healthcare provider order and prescription, and prior to arriving at the infusion unit. However, infusion unit staff should confirm that the patient has received the EUA Fact Sheet and that treatment and monitoring plan has been discussed with the patient. Provide the patient or caregivers with information on what to expect when they arrive at the infusion unit. Inform patients and caregivers that treatment could take about 3 hours and that treatment is administered via an infusion, NOT an injection.
- **Implement a patient registration and scheduling process:** Patient registration and appointment scheduling should be managed according to the local institution process. If there is no existing process or system, the infusion unit will need to establish one (e.g., online or call center). If walk-in appointments are accepted at the infusion unit, the unit must establish a process to manage these appointments.
- **Personal Protective Equipment (PPE) practices:** Reference local procedure for recommended PPE practices (e.g., how frequently to change masks, gowns, etc.). All staff should undergo appropriate PPE fitting and evaluation prior to arriving at any COVID-19 infusion unit.
- **Hypersensitivity reactions:** Each Infusion Unit will have a process in place to monitor for, diagnose and manage infusion and hypersensitivity reactions.
- **Infusion unit security:** Establish the appropriate process and staffing for security of the infusion unit.
- **Translation service:** Each unit should have a system in place to manage patients who require translation assistance.
- **Patient conveniences:** Individual units should determine how they will manage the overall patient experience. Considerations may include the use of personal electronic devices, reading materials and blankets, etc. The unit should also consider accommodation of patients with children, mobility issues and minor patients requiring parents/guardians to be in attendance.
- **Population of patients with COVID-19:** Each patient will likely present with various stages and levels of COVID-19 symptoms which may require accommodation, such as bathroom breaks throughout the process, vomiting and dizzy spells.
- **Waste management:** Refer to local procedures for waste management.
- **Hospital proximity:** Ideally, infusion units should be located within 5 miles of a hospital or emergency services.
- **Ventilation and air exchange:** Infusion units should understand ventilation and room air exchange rates and accommodate these into their SOPs for PPE use.

SECTION 06

# Appendices: Quick Reference Guides

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

# APPENDIX A: PATIENT INFUSION FLOWSHEET

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

**Patient Infusion Flowsheet**

COVID-19 Patient Infusion Center

**Phone:** (____)-____-_____ **Fax:** (____)-____-_____ **Date (mm/dd/yyyy):** __ / __ / ____

**Appointment Time:** __:__ am/pm **Prescribing healthcare provider and Phone:** _____

*Patient completes this section*

## PATIENT ADMIT

**First Name:** _____ **Middle Initial:** ___ **Last Name:** _____

**Date of Birth (mm/dd/yyyy):** ___/___/___ [ ] Male [ ] Female [ ] Other [ ] Decline to Answer

**Preferred Phone #:** (___)-____-_____ **Backup Phone #:** (___)-____-____

**Patient agrees to be contacted on:** [ ] Preferred Phone [ ] Backup Phone

**Emergency Contact Name and Phone#:** _____

**Allergies:** _____

History of any of the following: [ ] Asthma [ ] Beta-blocker use (e.g. metoprolol, atenolol)

[ ] Malignancies [ ] Auto-immune disease [ ] Previous severe medication allergy

*Do not write below this line – to be completed by unit staff only*

**Has patient received copy of Fact Sheet?** [ ] Yes [ ] No

**Signature of person completing this section:** _____

**Date (mm/dd/yyyy):** __ / __ / ____

## PREPARATION FOR INFUSION

Education provided on Infusion Reaction Signs/Symptoms — Initials: _____

**Baseline VS:**

| Time | Systolic BP | Diastolic BP | Heart Rate | Respirations | Temperature | SaO2 | Initials |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

Are vitals appropriate to proceed with infusion? [ ] Yes [ ] No | *If NO, contact physician*.

## IV PLACEMENT

**Location**: _____ **Catheter Size**: _____ **Time**: _____ am/pm **Initials:** _____

**Notes:**_____

_____

**Signature of person completing this section:** _____

**Date (mm/dd/yyyy):** __ / __ / ____

## INFUSION ADMINISTRATION

**Medication Infused Name/Dose:** _____ **Lot Number:** _____

**Administration Method:** [ ] Pump [ ] Gravity **Infusion Rate:** _____mL/hr

| | Date | Time | Initials |
|---|---|---|---|
| Start infusion | | | |
| End infusion (post saline flush) | | | |

**NOTE:** Monitor patient for changes in symptoms (e.g., itching, redness, difficulty breathing, difficulty swallowing, dizziness, increased coughing, nausea), and manage according to local/institution requirements. See Appendix B: Infusion Reactions for additional considerations.

**Earliest time patient can be released after observation (e.g., 60 minutes after end of infusion completion in accordance with Fact Sheet):** _____ am/pm | **Initials:** _____

**Signature of person completing this section:** _____

**Date (mm/dd/yyyy):** __ / __ / ____

## POST-INFUSION OBSERVATION

**NOTE:** Monitor patient for changes in symptoms (e.g., itching, redness, difficulty breathing, difficulty swallowing, dizziness, increased coughing, nausea), and manage according to local/institution requirements. See Appendix B: Infusion Reactions for additional considerations.

Did patient experience changes in symptoms? [ ] Yes [ ] No | *If YES, document details and treatment on Infusion Reaction Form.*

**Vital signs at end of observation period:**

| Time | Systolic BP | Diastolic BP | Heart Rate | Respirations | Temperature | SaO2 | Initials |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**Time intravenous line discontinued:** _____ am/pm | **Initials:** _____

Is the patient complaining of itching, redness, difficulty breathing, difficulty swallowing or feeling different in any way? [ ] Yes [ ] No | *If YES, follow unit protocol for management of infusion reactions and document on Infusion Reaction Form.*

**Signature of person completing this section:** _____

**Date (mm/dd/yyyy):** __ / __ / ____

**NOTE:** Report any SAE according to instructions in the Fact Sheet.

## PATIENT RELEASE

**Patient Signature:** I agree that I have received and understand contact information and follow-up instructions, and my questions have been adequately answered.

**Patient Signature:** _____ **Date (mm/dd/yyyy):** __ / __ / ____

**Releasing Provider:** _____ **Date (mm/dd/yyyy):** __ / __ / ____

**Release Time:** _____ am/pm

# APPENDIX B: INFUSION REACTIONS

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

**Infusion Reactions (Hypersensitivity Monitoring):**

- All participants should be monitored closely, as there is a risk of infusion reaction and hypersensitivity (including anaphylaxis) with any biological agent.
- Symptoms and signs that may occur as part of an infusion reaction include, but are not limited to: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia and dizziness.
- Severity of infusion-related reactions will be assessed and reported. An example of an accepted grading system is the Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Corrected Version 2.1 (July 2017) shown below.

**Example: Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Corrected Version 2.1 (July 2017)**

| Parameter | Mild | Moderate | Severe | Severe and Potentially Life-threatening |
|---|---|---|---|---|
| **Acute Allergic Reaction** | Localized urticaria (wheals) with no medical intervention indicated | Localized urticaria with intervention indicated<br>OR<br>Mild angioedema with no intervention indicated | Generalized urticaria<br>OR<br>Angioedema with intervention indicated<br>OR<br>Symptoms of mild bronchospasm | Acute anaphylaxis<br>OR<br>Life-threatening bronchospasm<br>OR<br>Laryngeal edema |
| **Cytokine Release Syndrome*** | Mild signs and symptoms<br>AND<br>Therapy (that is, antibody infusion) interruption not indicated | Therapy (that is, antibody infusion) interruption indicated<br>AND<br>Responds promptly to symptomatic treatment<br>OR<br>Prophylactic medications indicated for ≤24 hours | Prolonged severe signs and symptoms<br>OR<br>Recurrence of symptoms following initial improvement | Life-threatening consequences (for example, requiring pressor or ventilator support) |

*A disorder characterized by nausea, headache, tachycardia, hypotension, rash and/or shortness of breath.

**Management of Infusion Reactions On-Site**

- The clinical site should have necessary equipment and medications for the management of any infusion reaction, which may include but is not limited to: oxygen, barrier masks for CPR, epinephrine, albuterol inhalers, diphenhydramine injections, Solu-Medrol injections, IV steroids and 0.9% sodium chloride flush and bags.
- Recommended monitoring includes assessing patients for any new symptoms or changes in their physical exam every 10–15 minutes.
- Clinicians should determine the severity of the infusion reaction and manage infusion reactions based on standard of care and their clinical judgment. If an infusion reaction occurs, then supportive care should be used in accordance with the signs and symptoms.

# APPENDIX C: CENTRAL LINE ACCESS AND CARE

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

**How to prepare for patients who have a central line (PICC, Broviac, Port):**

Infusion sites of care will need to determine how they will manage patients with central lines. This will need to follow state and national guidelines as well as processes for that institution. In the event there are no overarching institutional processes, the infusion unit will need to create them.

For example, infusion units may establish any of the following guidelines:

- To access and use central lines, personnel must be experienced in the use of central lines and qualified per local requirements.
- DO NOT access the central line and place a peripheral IV to infuse the antibody.
- Refer these patients to a hospital setting for infusion.

# APPENDIX D: PERSONAL PROTECTIVE EQUIPMENT (PPE)

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

Healthcare providers in close contact with COVID-19 and who enter the room of a patient with a suspected or confirmed SARS-CoV-2 infection should use:

- NIOSH-approved N95 or equivalent or higher-level respirator (or facemask if a respirator is not available)
- Gown
- Gloves
- Eye protection (face shield or goggles)

See Appendix E: Cleaning and Sanitizing Considerations in a COVID-19 Environment for more information about guidelines for cleaning and sanitizing PPE and other equipment.

**Please refer to the following resources for more information:**

- **https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html**
- **https://www.cdc.gov/coronavirus/2019-ncov/downloads/A_FS_HCP_COVID19_PPE.pdf**
- **https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html#ref7**
- **https://www.mountsinai.org/files/MSHealth/Assets/HS/About/Coronavirus/MSHS-COVID-19-PPE-Practices.pdf**

# APPENDIX E: CLEANING AND SANITIZING CONSIDERATIONS IN A COVID-19 ENVIRONMENT

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

**Follow these cleaning and sanitization guidelines:**

- Sanitize hands after removing face mask or eye protection before touching face.
- All surfaces in contact with patients must be sanitized in between uses. These surfaces include chairs for infusion and all equipment (blood pressure cuff, pulse oximeter, stethoscopes, etc.).
- Gloves and gowns must be discarded after each use, when the healthcare provider plans to leave the infusion area, or when they are visibly soiled or torn.
- Goggles and reusable N95 masks or respirators must be disinfected in between each use.

**For COVID-19 disinfectants, surface types and contact time required, please visit:**

- https://cfpub.epa.gov/giwiz/disinfectants/index.cfm

**For additional guidance on disinfecting, please visit:**

- https://www.epa.gov/sites/production/files/2020-04/documents/316485-b_reopeningamerica_combo_placard_infographic_4.19_6pm.pdf

# APPENDIX F: PATIENT RELEASE INFORMATION

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

### Guidance for Patients at Discharge

After your infusion, bruising may occur at your IV site. This is normal. Elevating your arm and using cool compresses at the site may help. Please call your healthcare provider for any redness, swelling or drainage at the IV site as these may be signs of an infection.

You must be aware of possible symptoms after receiving a monoclonal antibody infusion.

**Mild reactions including localized urticaria (hives)** may occur 20 minutes to 36 hours after the infusion. If these occur, please call your healthcare provider. If you cannot reach them immediately, take diphenhydramine (e.g., Benadryl) as instructed (which may cause drowsiness). If symptoms do not improve or they worsen, go to your nearest Emergency room or call 911.

**Systemic reactions may include anaphylaxis and shock.** Although rare, severe allergic reactions can occur immediately after a monoclonal antibody infusion but also can occur up to 8 hours after infusion. Symptoms may include difficulty breathing, shortness of breath, wheezing, high-pitched breathing, feeling of your throat closing, persistent coughing, tongue lip and swelling, hives, itching all over, anxiety or confusion, heart palpitations and chest pain, flushing and warmth, abdominal pain or nausea and vomiting.

If these symptoms occur after leaving the infusion center, you should go to the nearest emergency room or call 911. If you are hospitalized for any reason, please tell the hospital that you received an antibody to treat COVID-19. Either you or the hospital must let the doctor who prescribed the antibody know about your hospitalization.

# APPENDIX G: GRAVITY FEED GUIDELINES

**Note:** All appendices in this manual are for example purposes only. Follow local guidelines and requirements.

**Follow these guidelines when using a gravity feed:**

- If an infusion pump is not available, mAb infusions may be administered via gravity feed by calculating the drip rate in drops per minute (gtt/min).
- Macrodrip tubing sets are either 10, 15 or 20 drops per 1 mL of fluid (gtt/mL).
- Count the drip rate for 1 full minute to ensure the rate is correct.
- The formula for calculating drip rate is as follows:

**Drip Rate Formula**

$$\frac{\text{Volume to be infused (in mL) x Drop factor (see tubing package)}}{\text{Total infusion time (in minutes)}} = \textbf{Drip rate (in drops/min)}$$