
# OWS Therapeutics: Monoclonal Antibody Playbook

Outpatient administration playbook version 2.0

**22 NOV 2020**

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***Product specific supplements to this playbook will also be made available by manufacturers***

# Introduction

# EUA Playbook Audience

This playbook is intended to support sites interested in administering COVID-19 treatment under EUA including:

- Existing hospital or community-based infusion centers
- Existing clinical space (e.g. urgent care, emergency depts)
- Ad hoc new infusion sites (e.g. "hospitals without walls")
- Long-term care facilities or home infusions with infusion delivery capability

Initial version of playbook focused on:

- Monoclonal antibody treatment
- Delivery via infusion
- Outpatient setting

This playbook will continue to evolve as other treatments and administration methods become available. We hope this playbook will be used to help healthcare facilities to implement monoclonal antibody treatment in an outpatient setting for those with COVID-19.

# Context of mAbs outpatient administration playbook

Proven **operationally challenging** to run mAbs clinical trials in **outpatient setting** for variety of reasons

Recent EUAs have been granted for Eli Lilly and Regeneron only **for outpatient setting**

Post EUA likely **high demand from sites** for accessing mAbs for outpatient treatment

**Few sites likely to have experience** with this type of procedure in an outpatient setting with COVID-19 patients

# Scope of this playbook

**Goal of playbook to articulate what is needed for outpatient administration to potential Tx sites:**

- **Supplies likely required** for administration and potential challenges in procurement
- **Personnel needed** for infusions
- **Space and logistics** needed to safely treat COVID-19 patients and protect others
- **Drug administration** process
- **Reimbursement** process
- **Reporting** process

***Elements currently out of scope***

- Process for site **engagement with state health departments** on ordering or reporting
- **Mechanisms for communication with United States Government** on allocation or distribution

To be addressed in future versions of the playbook

# Overview of therapeutic

Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus and are intended to **prevent progression of disease**

mAbs likely to be most effective when **given early in infection**

Product delivered via **single administration (e.g., IV infusion)**

**Early evidence** appears to suggest promise of mAb products in outpatient settings

- Early evidence from Eli Lilly mAb **showed potential to reduce hospitalization** for infected people if given early in infection in BLAZE-1 clinical trial
- Early evidence from Regeneron mAb cocktail data showed potential to decrease **viral load** and **reduced medical visits** in infected people if given early in the Outpatient 2067 clinical trial

# Possible patients eligible for treatment

Products granted EUA for **mild to moderate COVID-19 cases** early in infection, who are at **high risk for progressing to severe COVID-19 and/or hospitalization**; with following criteria

- Confirmation via **positive PCR or antigen test**
- Treatment **as soon as possible** following positive viral test and **within 10 days of symptom onset**
- Patient symptomatic but **not yet progressed to require hospitalization or oxygen therapy**

Treatment recommended just for **high-risk adult and pediatric patients 12 years and older >40 kgs:**

- High-risk defined by a combination of risk factors **such as**
  - Are ≥ 65 years of age or have a body mass index (BMI) ≥ 35
  - Are 12 – 17 years of age AND have BMI ≥85th percentile for their age and gender based on CDC growth charts

  *Please note above definitions represent examples of high-risk patients not full definition*

**Please reference EUA factsheets for specific treatment guidelines and detailed definitions of high-risk patients**

**For your awareness**
**(e.g. for patients not eligible for treatment under EUA):**

Monoclonal antibodies **under evaluation** for additional indications

**Participation encouraged** in clinical trials to assess additional drugs and indications

Clinical trial information available at

*http://www.riseabovecovid.org*

*Lilly clinical trials:*
https://blaze2study.com/
https://trials.lillytrialguide.com/en-US/

*Regeneron clinical trials*:
*https://www.regeneron.com/covid19*

# EUA summary: Eli Lilly Bamlanivimab

**The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA)** to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, 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 due to COVID-19, OR
- who require oxygen therapy due to COVID-19, 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

**Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19.** Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

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

For additional information– please reference EUA factsheet

## Key caveats

The EUA is for the use of the **unapproved product** bamlanivimab to treat COVID-19

Bamlanivimab is an **investigational drug** that has not been approved by the FDA for any use

It is **not yet known** if bamlanivimab is **safe and effective** for the treatment of COVID-19

This use is authorized **only for the duration of the declaration** that circumstances exist justifying the authorization of the emergency use, unless the authorization is terminated or revoked sooner

Health care providers must submit a report on **all medication errors and ALL SERIOUS ADVERSE EVENTS** related to bamlanivimab

# EUA summary: Regeneron (casirivimab/ imdevimab)

**The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA)** to permit the emergency use of the unapproved products casirivimab/ imdevimab to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) 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

**Casirivimab/Imdevimab are not authorized for use in patients:**

- who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, 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

**Benefit of treatment with casirivimab/imdevimab has not been observed in patients hospitalized due to COVID-19.** Monoclonal antibodies, such as casirivimab/imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

Casirivimab/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

For additional information– please reference EUA factsheet and RegeneronEUA.com

## Key caveats

The EUA is for the use of the **unapproved products** casirivimab/ imdevimab to treat COVID-19

Casirivimab/imdevimab are **investigational drugs** that have not been approved by the FDA for any use

It is **not yet known** if casirivimab/ imdevimab are **safe and effective** for the treatment of COVID-19

This use is authorized **only for the duration of the declaration** that circumstances exist justifying the authorization of the emergency use, unless the authorization is terminated or revoked sooner

Health care providers must submit a report on **all medication errors and ALL SERIOUS ADVERSE EVENTS** related to casirivimab/imdevimab

**Based on what we have learned to date - early administration of treatment needs fast testing turn-around and patient scheduling**

**Planning required for "Test and treat" or "Test and refer" models**

## Overview

- Treatment likely most beneficial to patients if given **early in symptom progression**
- EUA requires administration of **treatment as soon as possible after** confirmed positive test result and within **10 days of symptom onset**
- Strong **partnership and communication** between patients and HCP to get right treatment to right patients at right time
- Fast testing turnaround needed, to efficiently **identify positive tests** and **schedule for treatment**

## Example of timeline which would fulfill EUA requirements

| **Onset of symptoms** | **Clinical visit and diagnostic test** | **Confirmed positive test** | **Treatment** |
|---|---|---|---|
| | ***≤ 3 days** post symptom onset* | ***≤ 2 days** post diagnostic test* | ***≤3 days** post positive test result* |

**Treatment needed within 10 days of symptom onset**

*Testing sites should recommend COVID+ patients that are high risk confer with their HCP on potential suitability for Tx*

**Please reference EUA factsheet for specific treatment guidelines including recommended treatment window**

# Key challenges to overcome to allow for successful administration of mAb in outpatient setting

Drug ordering and storage | Pre-treatment | Treatment | Post-treatment | Communication on supply

*Out of scope of this playbook*

*For Additional Information Reference:*
*ASPR's Portfolio of COVID-19 Medical Countermeasures*

## Key challenges for administration

- Many sites **not adequately outfitted to do infusions** in outpatient setting (besides hospitals and ERs)
- Existing infusion centers currently **treat immune-compromised patients**, would need to be clear processes for COVID-19
- Pre-existing infusion centers potentially need to **adjust protocols** to treat **COVID-19-positive patients**
- **Lengthy infusion process** (up to 1 hour infusion followed by 1 hour post-infusion monitoring) needing dedicated space and personnel
- **Quick turn-around time for testing** needed to diagnose patients within window for treatment

***Please reference EUA factsheet for specific treatment guidelines***

*Out of scope of this playbook*

*For Additional Information Reference:*
*ASPR's Portfolio of COVID-19 Medical Countermeasures*

# Comprehensive checklist overview

# Plan of action to administer monoclonal antibodies under outpatient EUA

## Confirm your site wants to participate

- ❑ **Review needs** for treatment in outpatient settings
- ❑ **Ensure site prepared** to meet needs for treatment or willing to make required investments
- ❑ **Confirm site leadership supportive** of participation
  - ❑ Including senior clinical leadership (e.g., Chief Medical Officer)
- ❑ Approval of product for use by the hospital's **Pharmacy and Therapeutics Committee** (or equivalent committee)
- ❑ **Coordinate with State Chief Medical Officers** to confirm participation

## Prepare your site and staff for outpatient mAbs administration

- ❑ Ensure **sufficient supply** of needed materials for treatment
  - ❑ Infusion supplies, resuscitation equipment, etc.
- ❑ Develop **staffing and personnel** plan to support treatment
- ❑ Allocate **needed facilities and equipment** to support administration
- ❑ Ensure existing **infection prevention plan** sufficient
  - ❑ Adjust existing plan if needed to safely manage patient flow
  - ❑ Consider potential security requirements if needed
- ❑ Review **drug administration needs** with staff
- ❑ Inquire with hospital leadership about **reimbursement process**
- ❑ Prepare for **adverse events data tracking process**

## Develop procedures to identify and treat patients in timely manner

- ❑ **Prepare for scheduling and routing of referrals** from testing center or other HCPs to treatment
- ❑ Ensure hospital staff and doctors are **aware of outpatient treatment** availability
- ❑ Ensure **patient privacy** (HIPAA compliant) **maintained during** process
- ❑ Communicate to patient that EUA issued for investigational treatment but **does not constitute research** on behalf of the hospital

# Readiness checklist: Administration of outpatient mAbs under EUA

Allocate **dedicated space** and develop plan to **manage patient flow**

- ❑ Clear process for patients that are coming to clinical site including scheduling requirements
- ❑ Admission process for COVID-19 positive patients designed to minimize risk of spread per facility requirements / directions / guidelines'
- ❑ Dedicated room available for treatment

Ensure **dedicated source of supplies;** which may be difficult to procure

- ❑ Needed infusion components obtained
  - ❑ Example: IV kits, infusion chair, IV pole, vital sign monitoring equipment, emergency medications

Assign **sufficient personnel** to meet expected demand

- ❑ Sufficient staffing plans in place for Nurse/IV tech, Physician, Pharmacist
  - Likely need dedicated team to treat patients

Prepare for **drug administration** process

- ❑ Pre–visit: Clear treatment and monitoring plan developed for during infusion
- ❑ Treatment: 1-hour treatment and 1-hour post-treatment observation
  - ❑ Emergency protocol defined for addressing potential infusion reactions or complications
- ❑ Post-treatment: Clear process for patient follow-up defined using telemedicine as possible

Ensure **process for reimbursement** in place (non-drug administrative costs)

Prepare for **reporting needs** for adverse events and record keeping

# Activity 1: Define facilities and patient visit logistics

**Site will need dedicated outpatient COVID-19 treatment space**

**Dedicated COVID-19 patient area** with needed infusion supplies

- Some sites using COVID-19 waiting rooms for monitoring post infusion
- Rededication of existing clinical space acceptable under CMS Hospital Without Walls Initiative

**Immediate access to medications** to treat a severe infusion reaction, such as anaphylaxis, and the **ability to activate the EMS**, as necessary

*Select recommendations for outpatient setting, for more information reference CDC guidelines https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html*

# Alternate site of care allowances and needs

As part of **CMS Hospital Without Walls initiative**, hospitals can **provide services** outside of standard hospital settings

- **Other healthcare facilities** (e.g., urgent care clinics, doctors' offices etc)
- **Remote locations or sites** not normally considered healthcare facilities, (e.g., patient home via telemedicine, hotels, community site, temporary tents)
- **Nursing home or home health services** also likely to be acceptable sites of administration

Alternate site of care will need **same core capabilities and supplies** as typical site of administration

- Facility and patient flow needs (page 15 and 17)
- Supplies needed on site (e.g., rescue medication, infusion supplies, etc – page 23)

**Please reference CMS Hospitals Without Walls waivers and guidance for detailed information about program**

# Important to manage patient flow in a healthcare setting

- Have patient **wait to enter the site** until pre-scheduled time for treatment
- Ensure patient **wearing a mask or face covering** before entering the building
- Escort patient **directly to room, limit transport and movement of the patient outside of the room**
- Keep the **door closed** while patient in infusion room
- Medical and support personnel entering room need to **wear sufficient PPE** based on CDC guidelines
- Room should undergo **appropriate cleaning and surface disinfection** before it is returned to routine use

*Select recommendations for outpatient setting, for more information reference CDC guidelines*
*https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html*

# Pharmacy needs

**Infusion preparation process:**

- Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies
- Obtain new vial(s) and/or IV bags if the drug product contains any visible particulate matter

**Needs for space to prepare mAb drug:**

- Dedicated preparation area with sufficient capacity onsite or nearby

**Acceptable equipment for mAb drug storage:**

- Functional pharmacy sink
- Refrigerated storage (2-8° C)
- Temperature monitoring system with back-up
- Alarm system for notification to authorized personnel of temperature deviations/excursions in place

Please see EUA manufacturer fact sheet for drug-specific requirements

# Testing needs

**Outpatient monoclonal antibody product likely to need administration early in symptom progression**

- Treatment should be administered as soon as possible following positive test result, and within 10 days of symptom onset

**Fast turn-around testing capabilities key to identify patients and treat within this window**

- On-site point-of-care rapid testing or PCR tests ideal to provide quick diagnosis and treat patients on the same day
- Alternatives include partnership with off-site testing facility nearby with reliable and quick turnaround and robust patient tracking and reporting mechanism
  - Accelerated testing results turnaround likely recommended to allow for infusion early in disease progression

**Please reference EUA factsheet for detailed treatment guidelines including recommended treatment window**

# Product distribution and shipping information

- Manufacturer
- National distributor
- Government
- Site

**Federal and State government**

- Product will be **allocated equitably to each state and territory** by the Federal Government
- Product will be **allocated to individual sites** each week by **your State or Territory Health Authority**
  - Sites that would like to be considered for product allocation should contact their State or Territory Health Authority
- Once supply adequate to meet demand, site of care to order product as needed via AmerisourceBergen

**Manufacturer plant**

**Manufacturer warehouse**

**Amerisource Bergen**

- AmerisourceBergen will **proactively contact sites of care** that have received State or Territory Health Department allocations to **confirm acceptance of the allocation**
- Product will be **shipped refrigerated (2-8° C)** to your location by AmerisourceBergen

**Site of care**

**Patient**

# High level guidance on product shipping and storage

Product will be **shipped refrigerated (2-8° C)** to your location by USG distribution partners

Product should be **stored refrigerated (2-8° C)** before use

Target **shelf-life for product ~10 months at minimum**, follow guidance from manufacturer on expiration dates and product turnover

Prepared IV solutions are **intended for immediate patient administration.** If not used immediately:

- Solutions may be held at refrigerated conditions for example
  - Eli Lilly **no more than 24 hours**
  - Regeneron **no more than 36 hours**
- Solutions may be held at ambient light and room temperature conditions (including preparation, solution hold, infusion and flush) for example
  - Eli Lilly **no more than 7 hours**
  - Regeneron **no more than 5 hours**

**Please adhere to all guidelines for storage and use provided by manufacturer of EUA product**

# Activity 2: Ensure sufficient supplies

# Site supplies needed: Standard infusion supplies are needed but several components have been difficult to source

**Sites interested in providing outpatient infusions of mAbs to COVID+ patients should:**

1. **Confirm sufficient supplies of infusion materials**
2. **Proactively ensure items with long-lead times are sourced for your site**

***Ensure supplies sufficient to cover mAbs treatment in addition to day-to-day operations needs***

## *List of suggested supplies (not exhaustive)*

### PPE

- Gloves
- Gowns
- Eye and face protection (e.g. goggles, safety glasses, face shields)
- NIOSH-certified, disposable N95 filter facepiece respirators or better

### Infusion supplies

- Infusion chairs – *recommended only*
- IV pole
- IV administration sets
  - *PVC infusion set with/without DEHP containing 0.2 or 0.22 micron polyethersulfone (PES) in-line filter*
- IV and catheters
- 3mL saline syringes
- Appropriately sized syringes
- Alcohol wipes
- 2x2 gauze pads
- Adhesive bandages
- Tegaderm bio-occlusive dressing
- Absorbent underpads (blue pads)
- Extension set tubing
- Needles – stainless steel 18ga
- Sharps containers
- Transpore tape
- Transilluminator (vein finder)

### General supplies

- Infusion Reaction Kit
- Vital signs equipment
- 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 *(if required)*
- 70% alcohol wipes
- Paper towels
- Trash bins and liners

**Please reference EUA factsheet for final requirements**

# Activity 3: Develop plan for staffing and personnel

# Treating patients needs support of…

## HCP

**Prescribe monoclonal antibody** to patient, answer questions and **respond in case of emergency**

- Infectious disease or general HCP
- HCP will need to be on site for treatment
- At least 1 HCP should be able to respond to medical emergency (e.g., severe infusion reaction); any specific certifications based on state and healthcare facility regulations and policies

## Pharmacist

**Prepare the infusion,** answer questions and support with monoclonal antibody storage

- Pharmacy does not need to be physically located at the site of infusion

## Nurses

**Administer patient infusion** (up to 1 hr) and monitor patient wellbeing (1 hr)

- May require 2 nurses to start infusion, nurse practitioner to oversee larger infusion unit (if needed)
- Experienced phlebotomist needed as often difficult to find vein in patients (often high BMI and dehydrated)

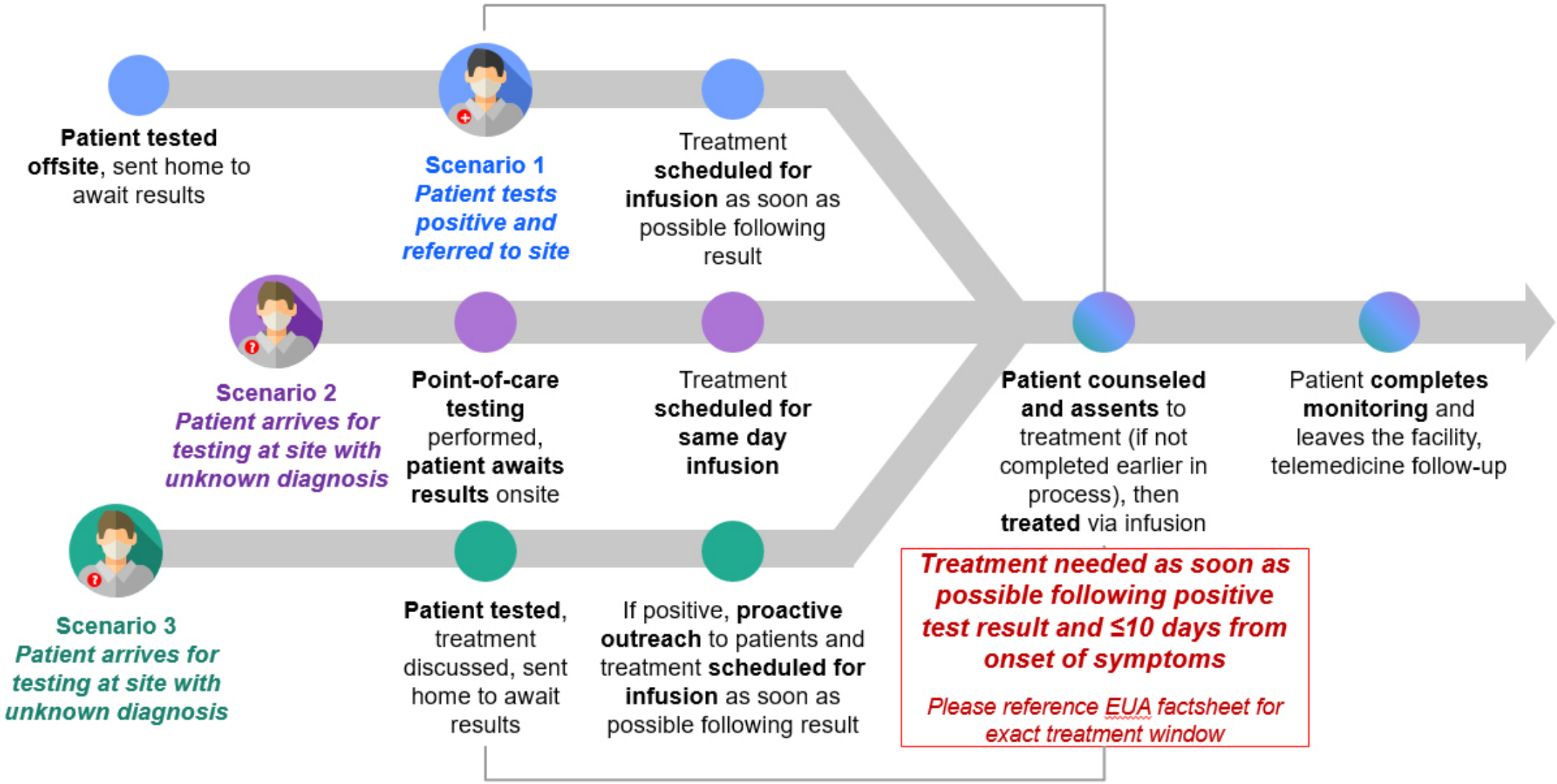
**Please reference EUA factsheet for specific treatment guidelines**

# Needed roles and responsibilities for site

| Role | Needed skills/profile |
|---|---|
| **Patient intake** | Scheduling and administrative skills |
| **Drug preparation** | Pharmacist or pharmacy technician trained in IV preparation |
| **Infusion: Start IV** | Nurse or other HCP trained to begin an IV |
| **Infusion: Administer infusion** | Nurse or other HCP trained in administering an IV |
| **Infusion monitoring** | Nurse or other HCP trained in vital sign monitoring |
| **Post infusion observation** | Nurse or other HCP trained in vital sign monitoring |
| **Patient release** | Administrative skills |
| **Cleaning** | Person trained in COVID cleaning / disinfection |

# Activity 4: Review drug administration process

# Three potential treatment pathways for symptomatic COVID-19 patients to receive care



# Patient flow for outpatient mAbs product

## *Scenario 1: Confirmed positive patient referred for treatment*

### Pre-treatment

**Confirm documentation of COVID-19 infection via either**

- Participant-provided lab report
- Medical record lab report
- Direct communication from a provider or laboratory

**Discuss treatment with patient**

- Ensure patient meets treatment requirements and understands risks

**Schedule the patient to come in for treatment ASAP**

- Provide guidance on site visit protocols to patients
- Provide patient education on what to expect with infusions

***Pre-treatment steps should be completed via telemedicine as possible (~30 mins)***

### Treatment

**Pre-book time for infusion space and follow clear protocol for coming onsite**

- Ensure operationally ready to receive and treat the patient
- Use CDC recommended practices to minimize exposure to others

**Provide treatment to patient**

- Infusion duration up to 1 hr with an additional 1 hr of observation post infusion (checks during infusion and observation)
- Infusion pumps or gravity-based infusion acceptable
- Ensure adequate staffing

**Ensure preparation for infusion reactions as unlikely but possible side effect**

- Infusion rate may be reduced based on patient circumstances
- Ensure emergency action plan in place; ability to activate EMS if necessary, a requirement for administration under EUA

### Post-treatment

**Discharge patient immediately following monitoring completion**

- Follow clear protocol to minimize risk of exposure to others

**Post-treatment care encouraged to be via telemedicine as possible**

- Normal follow-up care, no special data tracking requirements

# Patient flow for outpatient mAbs product

## *Scenario 2 and 3: Patient arrives for testing at site with unknown diagnosis*

*Same process as Scenario 1*

### Pre-treatment

**Direct patient to typical testing process for site (onsite or offsite)**

- Quick response testing needed for early diagnosis to enable early treatment

**Assuming patient discharged to await test results, once patient confirmed positive outreach on treatment *(~30 mins)* :**

- Discuss treatment with patient
  - Ensure patient meets treatment requirements and understands risks
  - Provide guidance on infusions and site visit protocols to patients
- Schedule the patient to come in for treatment ASAP
- Pre-treatment discussion and scheduling should be via telemedicine as possible

**In case of point-of-care rapid testing, consider same-day infusions. Needs**

- Isolated location for patient to wait
- Availability of infusion space and staff

### Treatment

**Pre-book time for infusion space and follow clear protocol for coming onsite**

- Ensure operationally ready to receive and treat the patient
- Use CDC recommended practices to minimize exposure to others

**Provide treatment to patient**

- Infusion duration up to 1 hr with an additional 1 hr of observation post infusion (checks during infusion and observation)
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### Post-treatment

**Discharge patient immediately following monitoring completion**

- Follow clear protocol to minimize risk of exposure to others

**Post-treatment care encouraged to be via telemedicine as possible**

- Normal follow-up care, no special data tracking requirements

# Product preparation guidelines

| Product | Eli Lilly | Regeneron | | | |
|---|---|---|---|---|---|
| Vials provided | • 20 mL vial of Bamlanivimab | • 11.1 mL vial Casirivimab<br>• 11.1 mL vial Imdevimab | • 11.1 mL vial Casirivimab<br>• 2.5 mL vial Imdevimab | • 2.5 mL vial Casirivimab<br>• 2.5 mL vial Imdevimab | • 2.5 mL vial Casirivimab<br>• 11.1 mL vial Imdevimab |
| Initial 0.9% saline bag required | • 250 mL | • 250 mL | • 250 mL | • 250 mL | • 250 mL |
| Required saline to remove from bag | • 70 mL | • 20 mL | • 20 mL | • 20 mL | • 20 mL |
| Volume product to withdraw from vial(s) and dilute in bag | • 20 mL Bamlanivimab from 1x 20mL vial | • 10 mL Casirivimab from 1x 11.1 mL vial<br>• 10 mL Imdevimab from 1x 11.1 mL vial | • 10 mL Casirivimab from 1x 11.1 mL vial<br>• 10 mL Imdevimab from 4x 2.5 mL vial | • 10 mL Casirivimab from 4x 2.5 mL vial<br>• 10 mL Imdevimab from 4x 2.5 mL vial | • 10 mL Casirivimab from 4x 2.5 mL vial<br>• 10 mL Imdevimab from 1x 11.1 mL vial |
| Final volume of product in IV bag | • 200 mL | • 250 mL | • 250 mL | • 250 mL | • 250 mL |

# Activity 5: Prepare for reimbursement and ordering

# Reimbursement process for mAbs therapeutic under EUA

**Connect with state or territory health authority** on appropriate ordering procedures to receive mAbs product

Under initial phase of treatment (likely through 2020), **drug cost likely to be paid by US government** under advanced purchase agreements

**Confirm internally with your site** administration on reimbursement for **non-drug costs** (e.g., infusion services, pharmacy)

Please **reference CMS resources** for more information

- **Provider toolkit:** https://www.cms.gov/covidvax
- **COVID FAQs:** https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

# Activity 6: Reporting process

# Reporting needs

Sites receiving monoclonal antibody will follow established mechanisms for tracking and reporting **serious adverse events**

- Events that are potentially attributable to monoclonal antibody use must be reported to the FDA
  - Refer to the Fact Sheet for Healthcare Providers as part of EUA for guidance
  - Complete and submit a MedWatch form or complete and fax FDA Form 3500 to report

Site must **maintain records** regarding use of the monoclonal antibody by patients

- **Inventory information:** e.g., lot numbers, quantity, receiving site, receipt date, product storage
- **Patient information:** e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered

USG will track product delivery through the commercial distributor and CMS systems

Ensure that any records associated with this EUA are **maintained for inspection** upon request


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# Thank you!