



## OWS Therapeutics Pre-EUA Playbook – Monoclonal Antibodies

Outpatient administration playbook

02 NOV 2020; VERSION 1.0

#### Pre-EUA Playbook Audience

\*Information in this playbook will be adjusted based on FDA guidance. This initial guidance should be used to help with preparedness 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")

#### 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 start planning on how to implement monoclonal antibody treatment in an outpatient setting for those with COVID-19.

## 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 data showed potential to reduce viral load compared to placebo through Day 7 in seronegative patients

Working assumption subject to change based on EUA conditions

#### Possible patients eligible for treatment

Product potentially could be granted EUA for **mild to moderate COVID-19 cases** early in infection, with following criteria

- Confirmation via positive PCR or antigen test
- Treatment early in the progression of the disease recommended to ensure mAb most effective
- Patient symptomatic but not yet progressed to require hospitalization

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

- High risk likely to be defined by a combination of risk factors such as
  - Are ≥ 65 years of age or have a body mass index (BMI) ≥ 35

Please reference any ultimate EUA factsheet for specific treatment guidelines

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

Riseabovecovid.org http://insight-trials.org/

Lilly clinical trials: <u>https://blaze2study.com/</u> <u>https://trials.lillytrialguide.com/en-US/</u>

Regeneron clinical trials: <u>https://www.regeneron.com/covid19</u>

#### Working assumption subject to change based on EUA conditions

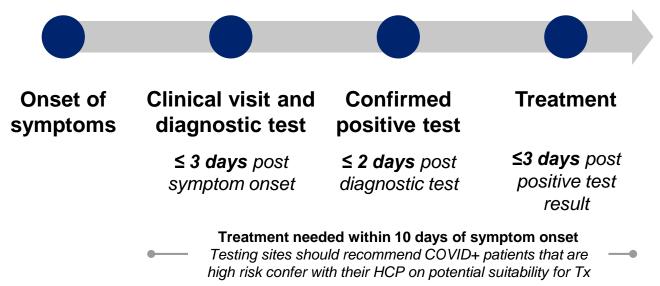


Based on what we have learned to date - early administration of treatment needs fast testing turnaround and patient scheduling

#### **Overview**

- Treatment likely most beneficial to patients if given early in symptom progression
- EUA likely to require administration of **treatment within 3 days** of 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 timeline**



Please reference any ultimate 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** Pre-Post-**Communication on Treatment** treatment treatment supply storage 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 Out of scope of Out of scope of this playbook this playbook **Lengthy infusion process** (up to 1 hr infusion followed by postinfusion monitoring) needing dedicated space and personnel Quick turn-around time for testing needed to diagnose patients within window for treatment Please reference any ultimate EUA factsheet for specific treatment guidelines

## **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)

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 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 up to 6 hours post-treatment observation
  - □ Emergency protocol defined for addressing potential infusion reactions or complications
- Dest-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

To be included in next potential version of playbook to be released following an EUA as relevant

# 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

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



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)

Alternate site of care **must be linked to hospital** to allow for reimbursement of medical services

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

- Facility and patient flow needs (page 10)
- Supplies needed on site (e.g., rescue medication, infusion supplies, etc – page 17)

#### Working assumption subject to change based on EUA conditions



#### **Pharmacy needs**

#### Infusion preparation process:

- Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies
- If a laminar flow hood is available, it is recommended for dose solution preparations
- Use aseptic technique and applicable good clinical practice for intravenous solution preparations
- 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
- Prep room that allows aseptic techniques

#### 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

Drug-specific requirements will be added when available

#### Working assumption subject to change based on EUA conditions



#### **Testing needs**

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

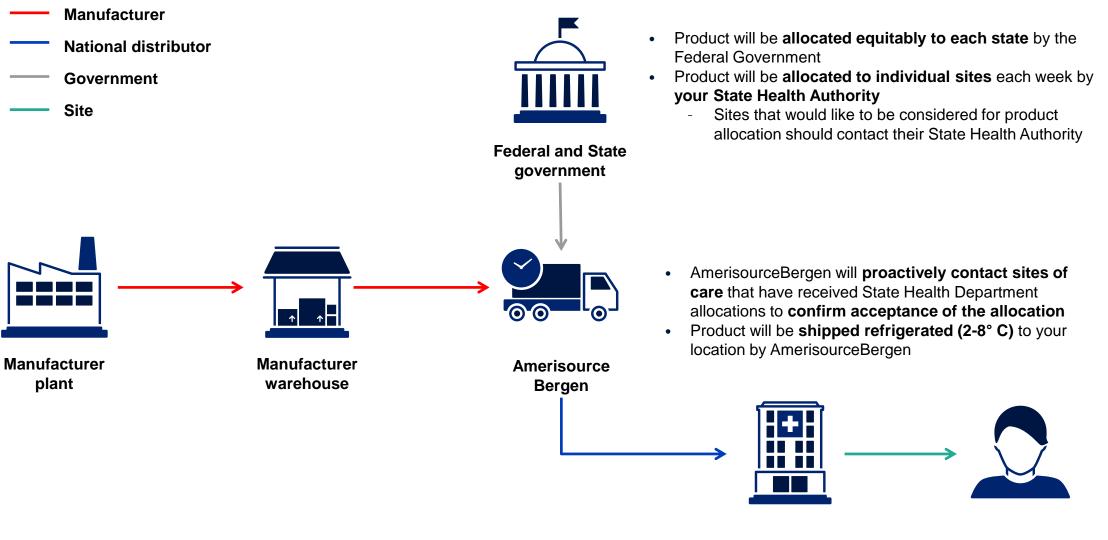
 Treatment likely to be required within 3 days of positive test result, and within 10 days of symptom onset

## 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
  - Testing results turnaround within 2 days likely recommended to allow for infusion early in disease progression

Please reference any ultimate EUA factsheet for detailed treatment guidelines including recommended treatment window

#### **Product distribution and shipping information**



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 no more than 24 hours
- Solutions may be held at ambient light and room temperature conditions for example no more than 7 hours
  - Hold time includes preparation, solution hold, infusion and flush

### Please adhere to all guidelines for storage and use provided by manufacturer of ultimate 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

#### PPE

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

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

#### 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 guidelines for final requirements**

#### **Pharmacy supplies needed**

#### List of needed supplies

Sterile empty PVC infusion bag with or without DEHP

1 unit of 0.9% Saline per dosing

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## Activity 3: Develop plan for staffing and personnel



Treating patients needs support of...

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

Infectious disease or general HCP

**Pharmacist** 

- HCP will need to be on site for treatment
- At least 1 HCP should have Advanced Cardiovascular Life Support (ACLS) certification or equivalent

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

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

HCP



Administer patient infusion (up to 1 hr) and monitor patient wellbeing (up to 6 hrs)

- 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 any ultimate EUA factsheet for specific treatment guidelines







## Thank you!