



# Update: Allocation and Distribution of OWS Therapeutics

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NOVEMBER 4, 2020

# Context

- **Veklury (remdesivir) remains the only FDA-approved product for the treatment of COVID-19.**
- **A spectrum of therapeutics is currently under consideration.**
- **USG is planning for the allocation and distribution of Operation Warp Speed therapeutic products.**
- **We seek to leverage and refine the process initially used with remdesivir allocation and distribution.**

## Topics for today

- Provide update on status of OWS therapeutics development
- Summarize process for allocation and distribution of products
- Discuss anticipated unique drug administration requirements and anticipated challenges; pre-EUA playbook



# Overview of Veklury (remdesivir) experience

Following the EUA approval of remdesivir for the treatment of COVID-19 on May 1, **HHS/ASPR established a team to oversee the fair and equitable allocation and distribution of the drug**

Understanding the team's experience provides the foundation for designing the distribution process for OWS Tx products **and is instructive for distribution in inpatient clinical uses**

HHS/ASPR Regional Teams played a critical role in the remdesivir process and **will be a vital part of the allocation and distribution of future COVID-19 therapeutics**

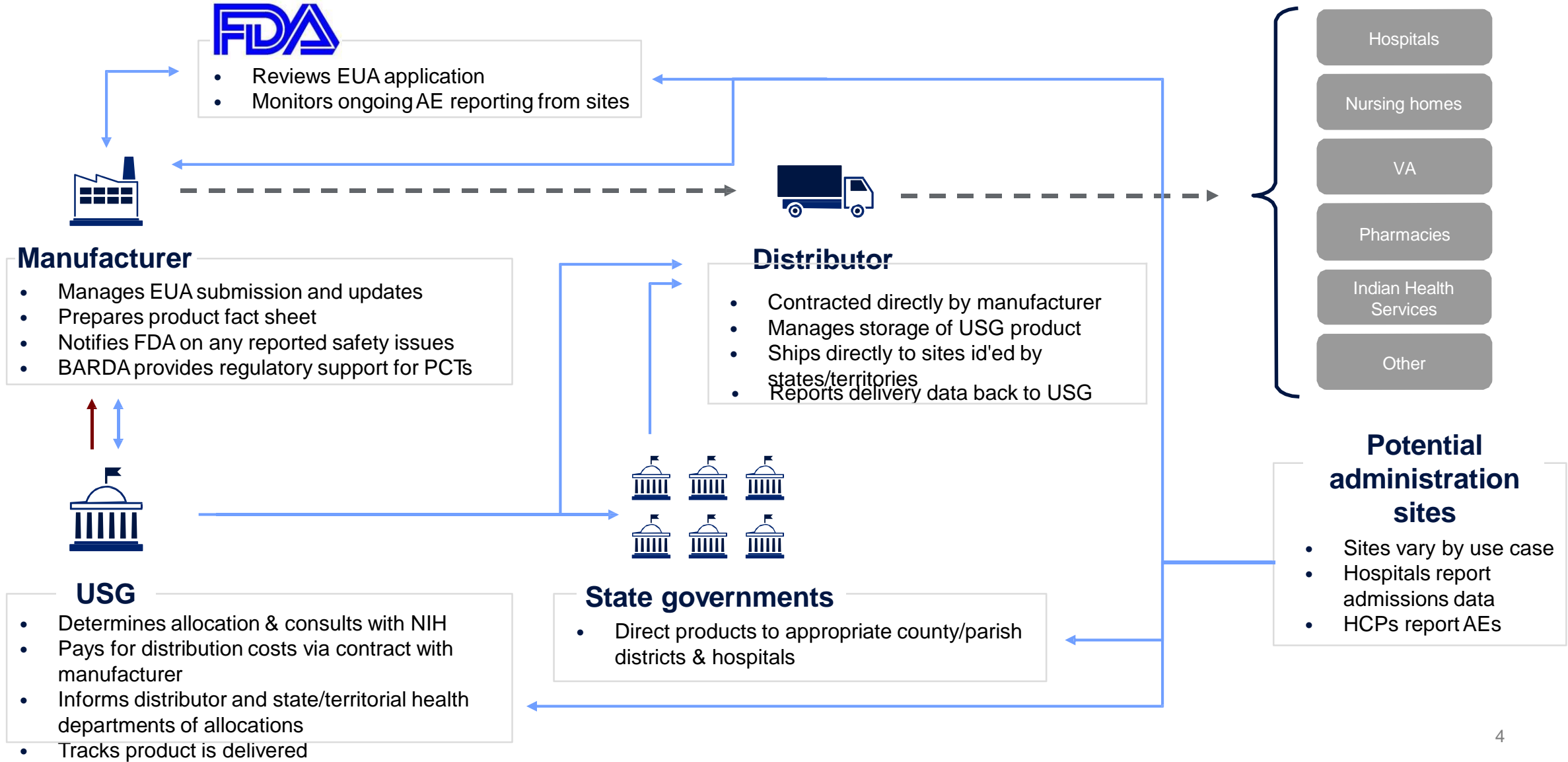
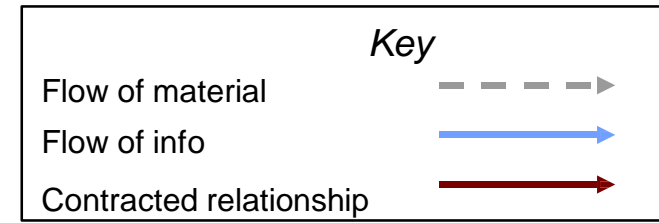


# Principles for USG allocation and distribution

- 1 Maximize use of existing infrastructure within USG, manufacturer and distributor channels
- 2 USG to allocate to state governments when product is scarce
  - Allocations must ensure both *temporal* and *geographic* equity
- 3 States responsible for allocation to final points of care
- 4 Manufacturer tracks pharmacovigilance and follows mandatory reporting guidance



# Allocation and distribution concept of operations



# Federal allocation decision informed by two data sources from HHS Protect

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## ***Confirmed Hospitalizations (7- Day Incident)***

- Entered daily via TeleTracking (HHS Protect) at hospitals: “How many confirmed COVID-19 cases admitted in last 24h period?”
- Data has a known lag, as it typically takes 1-2 weeks for hospitalization of patients
- Complete and timely (98% of facilities report at least once weekly; 89% report daily)

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## ***Confirmed Cases (7- Day Incident)***

- All confirmed cases
- Contributes overall magnitude of case load
- Captures emerging cases in near real time

# USG supports distribution and administration of products



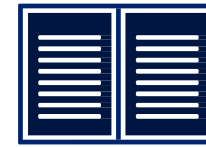
## Outlines ordering process

- Ensures allocations informed by latest dose availability information
- Encourages distributor to automate state/territory allocation process through web portal
- Provides training/guidance on process to stakeholders prior to EUA



## Engages with stakeholders

- Prior to EUA
  - Weekly standing calls with professional associations and state health departments
- With EUA launch
  - Website (phe.gov) with latest information and FAQs
  - Weekly calls & office hours
  - Formal request for information pathway
- Following EUA
  - Establishes weekly cadence for allocations



## Develops playbook for sites

- Goal is to generate preparation for anticipated administration needs:
  - Supplies likely required for administration and potential challenges in procurement
  - Personnel needed
  - Space and logistics needed to safely treat COVID-19 patients and protect others
  - Drug administration process
  - Reimbursement process
  - Reporting process

# Allocations expected to take place every Wednesday, with first doses delivered on Thursday following state/territory allocation





# Pre-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")

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.

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

## Pre-EUA 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 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

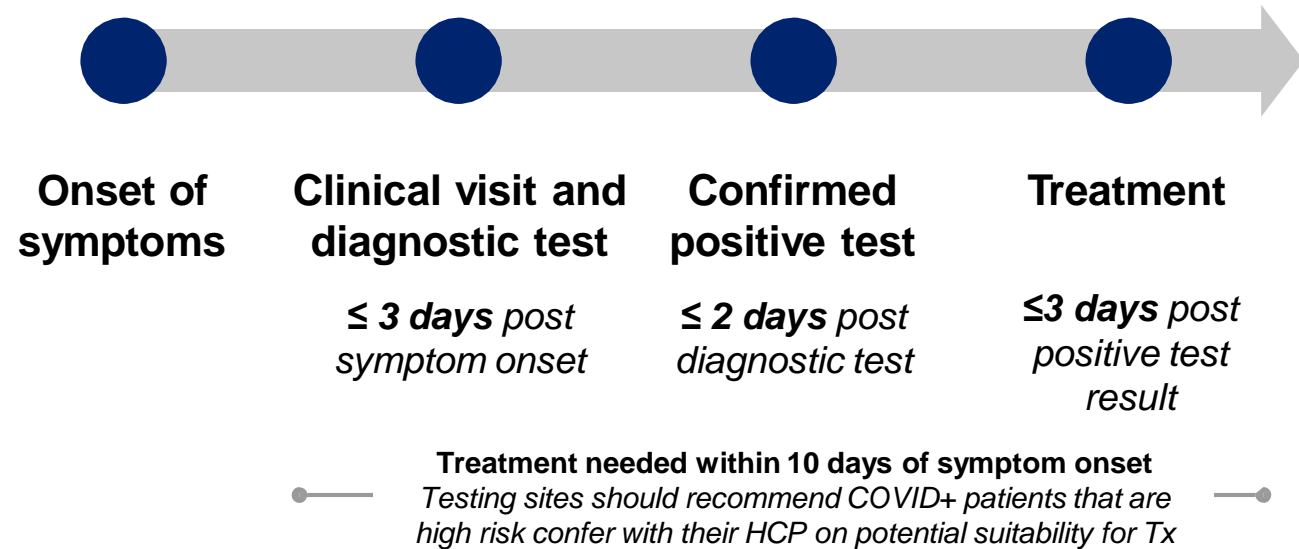


**Pre-EUA Playbook:**  
Based on what we have learned to date - early administration of treatment needs **fast testing turnaround and patient scheduling**

## 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

# 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 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

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



**Thank you!**