

# ASPR

ASSISTANT SECRETARY FOR  
PREPAREDNESS AND RESPONSE



## SPEED

# Special Projects for Equitable and Efficient Distribution of COVID-19 Outpatient Therapeutics

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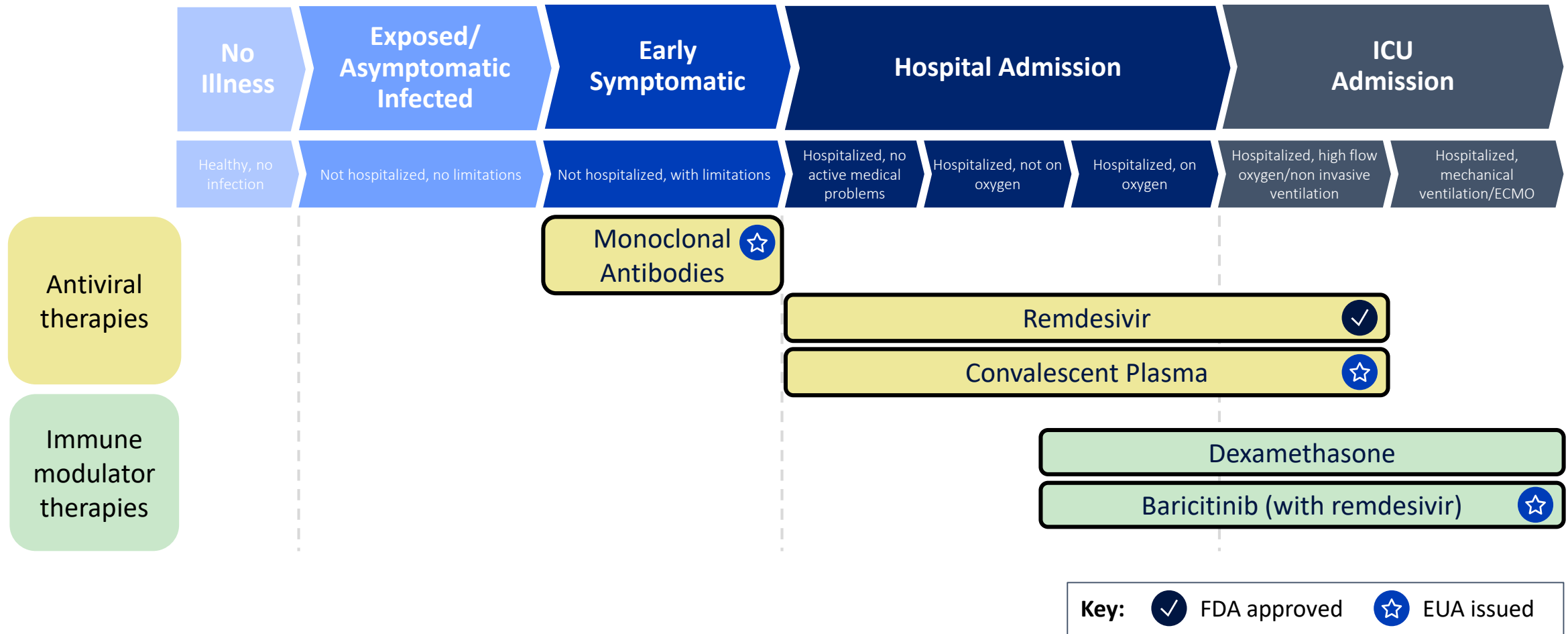
16 FEBRUARY 2021, PRESENTATION TO THE NEW YORK CITY HEALTH CARE COALITION (NYCHCC)

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# Overview of therapeutic options to treat COVID-19

# Interventions depend on stage of COVID-19 illness

Objective: optimize therapeutic use to prevent or shorten hospitalizations



# Two monoclonal antibody products are available under EUA

*Eli Lilly and Co. (bamlanivimab) and Regeneron Pharmaceuticals, Inc. (casirivimab and imdevimab)*

## Similarities across products

- **Patient population:** adults or pediatrics >12 years of age (>40Kg)
  - Excludes hospitalized patients
  - Allows use with pregnancy based risk/benefit
- **Factors** used **to define high risk** patients, based on CDC criteria.
- **Administration** considerations:  $\geq$  50 ml of 0.9% sodium chloride injection, filter, no pump required.
- **No dose adjustments** planned
- **Monitor** for at least **1 hr after infusion** complete

## Key Differences

	<b>REGN-COV2</b> <i>Casirivimab and imdevimab</i>	<b>Lilly</b> <i>Bamlanivimab</i>
<b>Drug Type</b>	mAb <b>combination therapy</b>	mAb <b>monotherapy</b>
<b>Preparation</b>	<u>Volume withdrawn from vial(s):</u> <ul style="list-style-type: none"> <li>• <b>10 mL each mAb</b></li> </ul> <u>Storage conditions:</u> <ul style="list-style-type: none"> <li>• up to <b>4hrs room temp</b> or <b>36hrs refrigerated</b></li> </ul>	<u>Volume withdrawn from vial(s):</u> <ul style="list-style-type: none"> <li>• <b>20 mL</b></li> </ul> <u>Storage conditions:</u> <ul style="list-style-type: none"> <li>• up to <b>7hrs room temp</b> or <b>24hrs refrigerated</b></li> </ul>
<b>Dosing</b>	<b>2400 mg</b> (1200mg each mAb co-administered)	<b>700 mg</b>
<b>Vial Size(s)</b>	<b>11.1 mL OR 2.5 mL</b> (same concentration)	<b>20 mL</b>
<b>Safety</b>	<b>1.5%</b> infusion reactions in high dose; 0% low dose	<b>2.3%</b> infusion reactions in treatment arms
<b>Minimum Infusion Time</b>	60 minutes	16 – 60 minutes

# Bamlanivimab Infusion Times

Drug: Add 20 mL of bamlanivimab (1 vial) to a prefilled infusion bag and administer as instructed below

<b>Size of prefilled 0.9% Sodium Chloride infusion bag</b>	<b>Maximum Infusion Rate</b>	<b>Minimum Infusion Time</b>
50 mL	270 mL/hr	16 minutes
100 mL	270 mL/hr	27 minutes
150 mL	270 mL/hr	38 minutes
250 mL	270 mL/hr	60 minutes

# Treatment eligibility

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 as patients who meet at least one of following criteria:

- |  |   |
|--|---|
| <ul style="list-style-type: none"><li>• Have BMI <math>\geq 35</math></li><li>• Have chronic kidney disease</li><li>• Have diabetes</li><li>• Have immunosuppressive disease</li><li>• Are currently receiving immunosuppressive treatment</li><li>• Are <math>\geq 65</math> years of age</li></ul> | <ul style="list-style-type: none"><li>• Are 12-17 years of age AND have<ul style="list-style-type: none"><li>- BMI <math>\geq 85^{\text{th}}</math> percentile for age/gender based on CDC growth charts, OR</li><li>- Sickle cell disease, OR</li><li>- Congenital or acquired heart disease, OR</li><li>- Neurodevelopmental disorders, OR</li><li>- A medical-related technological dependence, OR</li><li>- Asthma, reactive airway or other chronic resp. disease that requires daily meds/control</li></ul></li></ul> |
|--|---|

**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>

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# **SPEED Program**

## SPEED Overview

- Facilitate access to and utilization of mAbs among populations at high risk for hospitalization and severe disease:
  - Long-term care facilities
  - Dialysis centers
  - Federally qualified health centers (FQHCs)
  - Correctional facilities
- Direct allocation; targeted outreach and engagement with priority sites
- Separate and complementary to state-based mAb allocation system
- More information:
  - View SPEED website:  
<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx>
  - Contact [covidtx@hhs.gov](mailto:covidtx@hhs.gov)



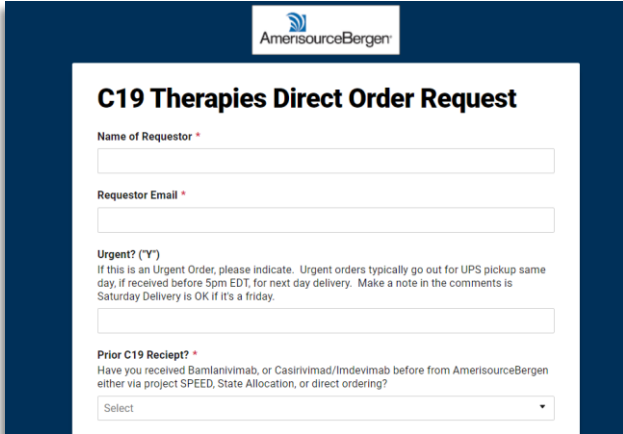
## SPEED Eligibility

- Priority settings and partners
- Have necessary capabilities to receive, prepare and administer mAbs, and monitor and respond to any infusion-related reactions
- Resources to help assess readiness:
  - **Bamlanivimab:**  
<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/Bamlanivimab-Baseball-Card.aspx>
  - **Casirivimab/Imdevimab:**  
[https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas\\_imd/Pages/Casirivimab-Imdevimab-Baseball-Cards.aspx](https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/Casirivimab-Imdevimab-Baseball-Cards.aspx)
  - **Federal Response mAb Playbook:**  
[https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook\\_1Feb2021.pdf](https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook_1Feb2021.pdf)
  - **Lilly Playbook:**  
<https://www.covid19.lilly.com/assets/pdf/bamlanivimab/lilly-antibodies-playbook.pdf>
  - **Regeneron Guidebook:**  
<https://www.regeneroneua.com/Content/pdf/treatment-covid19-eua-guide-book.pdf>

# Direct Ordering | Sites to place orders with ABC

## Ordering process...

- Separate form from typical ABC ordering portal for commercial products
- Sites indicate if they are an existing site (Path A) or new site (Path B)
- Sites confirm registration for TeleTracking/NHSN to report utilization or are requested to register for a new TeleTracking account



The screenshot shows a web form titled "C19 Therapies Direct Order Request" with the AmerisourceBergen logo at the top. The form includes the following fields and sections:

- Name of Requestor \***: A text input field.
- Requestor Email \***: A text input field.
- Urgent? (\*Y\*)**: A text input field. Below it is a note: "If this is an Urgent Order, please indicate. Urgent orders typically go out for UPS pickup same day, if received before 5pm EDT, for next day delivery. Make a note in the comments if Saturday Delivery is OK if it's a Friday."
- Prior C19 Receipt? \***: A dropdown menu with the option "Select". Below it is a note: "Have you received Bamlanivimab, or Casirivimab/Imdevimab before from AmerisourceBergen either via project SPEED, State Allocation, or direct ordering?"

### A *Site has received product before*

- Currently receiving mAbs as part of the other allocation pathways and need additional supply
- Site does not need to go through validation process
- Order fulfilled

### B *Site has not received product via allocation*

- Site validated prior to fulfillment either by ABC or by state department of health

Ordering link available at: <https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>

## Direct Ordering Process

- Sites will be required to:
  - Provide board of pharmacy license or physician letter of authorization
  - Attest to their designated class of trade and that they will administer the authorized product according to the terms of the FDA issued EUA
  - Provide Utilization data via either TeleTracking or NHSN
- Sites can order product based on established minimum amounts; subsequent orders are subject to a maximum amount based on previous orders and utilization
- State departments of health will be informed of therapies ordered within their jurisdictions for awareness
- More info on Direct Ordering:  
<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf>

## Data Collection

- All sites receiving USG-procured product are required to register with TeleTracking and provide information on monoclonal antibody therapeutic inventory and administration on a weekly basis.
- Future order fulfilment may be based on demonstration of adequate utilization of product to ensure appropriate distribution.
- If you do not have a TeleTracking account, one will be established for your facility after your first order.
  - You will receive enrollment and reporting instructions in an e-mail from [protect-noreply@hhs.gov](mailto:protect-noreply@hhs.gov) with the subject line of “Invitation: HHS TeleTracking COVID-19 Portal.”
  - If you do not receive an invite, please contact TeleTracking’s Technical Support at [hhs-protect@teletracking.com](mailto:hhs-protect@teletracking.com).

# TeleTracking | Reporting on COVID-19 Therapeutics

Allocations to states and distribution to individual sites dependent on **mandatory therapeutics reporting** to ensure product is being allocated/distributed appropriately



Casirivimab (REGN10933) / Imdevimab (REGN10987) (Therapeutic A)	Bamlanivimab (Therapeutic B)
39a. Current inventory on hand (in courses) ⓘ <input type="text" value="10"/>	39c. Current inventory on hand (in courses) ⓘ <input type="text" value="15"/>
39b. Courses used in the last week ⓘ <input type="text" value="7"/>	39d. Courses used in the last week ⓘ <input type="text" value="Unknown"/>

## Entering data into TeleTracking

- For each of the products in the Therapeutics section, enter in quantity of product **remaining on hand** and **used in the last week** quantity and press submit
- The number should be in **patient courses**

More info on TeleTracking:

<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx>

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# Long Term Care Facilities

## LTCF SPEED Partners

- SPEED supports LTCFs, including nursing homes and assisted living facilities, through partnerships with stakeholder and/or trade associations who assist with educating members and non-members about mAbs
- SPEED partners also help identify entities that are able and willing to administer mAbs
- Membership in partner associations is not required for participation in SPEED
- Partners include:
  - [National Home Infusion Association](#)
  - [American Society of Consultant Pharmacists](#)
  - [AMDA – The Society for Post-Acute and Long-Term Care Medicine](#)

# LTC Pharmacies/Home Infusion Centers Participating in SPEED to Date

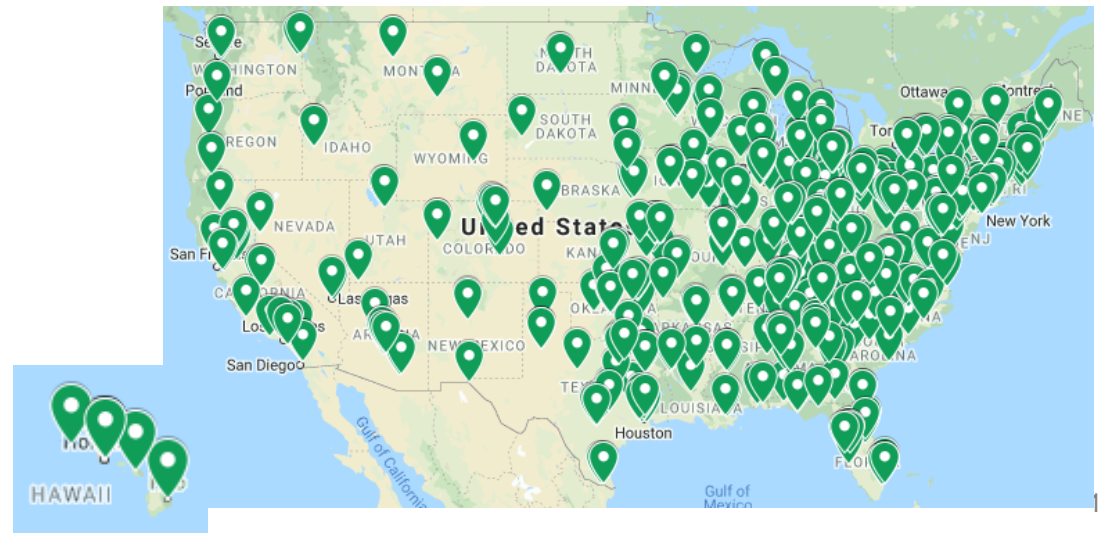
To date, **172 Home Infusion Centers** and **510 Long Term Care Pharmacies** – representing 49 states – are participating in SPEED

To date:

- **22,791** patient courses of **bamlanivimab** and **6** patient courses of **casirivimab/imdevimab** have been distributed to LTC Pharmacies
- **3,416** patient courses of **bamlanivimab** and **1** patient course of **casirivimab/imdevimab** have been distributed to home infusion providers



Home Infusion Centers



Long Term Care Pharmacies



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# Dialysis Centers

## Dialysis Partners

- SPEED engages with dialysis centers through outreach to stakeholder and/or trade associations who helped identify entities that may be willing to administer mAbs
- Partners include:
  - American Society of Nephrology
  - ESRD Network
  - Kidney Community Emergency Response
  - Renal Healthcare Association
- Additional outreach through State Departments of Health and direct to dialysis companies

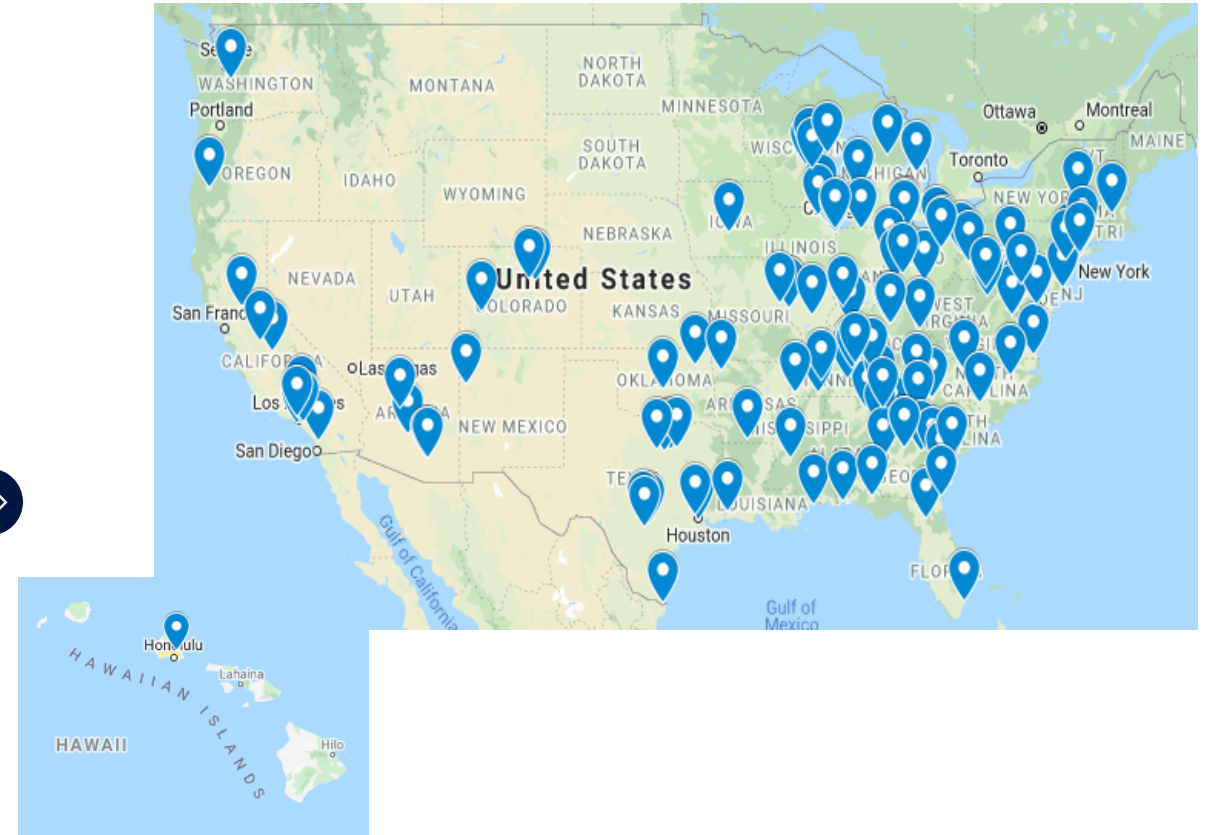
# Dialysis Centers Participating in SPEED to Date

To date, **186 facilities** – across 41 states – are participating in SPEED

## Variety among participants:

- Large dialysis companies, including Fresenius, DaVita, and US Renal Care
- Independent centers
- Hospital-based dialysis units

**Goal:** 300 participating dialysis facilities participating in SPEED by end of March



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# FQHCs

## FQHC SPEED Allocation Streams

- FQHCs and look-alike facilities with on-site administration capabilities may **receive mAbs directly**
- FQHCs and look-alike facilities without on-site capabilities to administer mAbs **can partner** with nearby hospitals or other facilities that do have the necessary capabilities.
  - Facilities will receive a direct allocation of mAbs that are **earmarked for use in FQHC patients only**
  - To enroll a partner facility, follow standard ordering instructions...
    - **PLUS**, in the facility name field, indicate the name of the partner facility and FQHC (e.g., Hospital A on behalf of FQHC B).

# FQHCs Participating in SPEED to Date

To date, **20 named entities** – representing almost 350 sites, across 10 states – are participating in SPEED

## Variety among participants:

- Rural and urban settings
- East to west coast
- Sizes range from ones that have 2-5 individual sites, to those with 27, 45, or even 137 sites

Nearly 800,000 total patients are served by FQHCs receiving product through SPEED – including many racial and ethnic minorities

**Goal:** Double number of participating FQHC sites by end of March



## FQHC administration options include:

- On-site administration (coupled with on-site testing)
- Mobile units
- Community partners (hospital, infusion center)
- Others

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# Correctional Facilities

## Correctional Onboarding Process

- Allocation Models:
  - Individual jails/prisons with on-site storage and administration capabilities may receive mAbs directly
  - Central/regional warehouses with storage capabilities may receive mAbs and distribute to individual facilities
  - Partnering retail pharmacies or contract pharmacies that support correctional facilities may receive mAbs
- Need email sign-off by Department of Corrections if other partners (e.g., contract pharmacy, Department of Health) initiate outreach



# Participating Correctional Facilities

- To date, **seven** states – representing almost 80 sites – are receiving product through SPEED to support their state and local correctional facilities
- In total, over 100,000 inmates have access to mAbs through SPEED
- **GOAL:** Facilitate mAb administration in correctional facilities across all 50 states!



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# **SPEED Contact Information and Resources**

## SPEED Contact Information

- **SPEED Website:**  
<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx>
- **SPEED FQHC Enrollment Guide:**  
<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED-enrollment-guide-fqhc.aspx>
- **Email:** [covidtx@hhs.gov](mailto:covidtx@hhs.gov)

# Tools/Resources

- ***mAb Administration Baseball Cards (review Resource/Links as well)***
  - **Bamlanivimab:** <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/Bamlanivimab-Baseball-Card.aspx>
  - **Casirivimab/Imdevimab:** [https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas\\_imd/Pages/Casirivimab-Imdevimab-Baseball-Cards.aspx](https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/Casirivimab-Imdevimab-Baseball-Cards.aspx)
- ***Administration playbooks***
  - **Federal Response mAb Playbook:** [https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook\\_1Feb2021.pdf](https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook_1Feb2021.pdf)
  - **Lilly Playbook:** <https://www.covid19.lilly.com/assets/pdf/bamlanivimab/lilly-antibodies-playbook.pdf>
  - **Regeneron Guidebook:** <https://www.regeneroneua.com/Content/pdf/treatment-covid19-eua-guide-book.pdf>

# Tools/Resources (cont.)

- ***Reimbursement information***

- **CMS Reimbursement rates:** <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>
- **HRSA FAQs for COVID-19 Claims Reimbursement:** <https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions>

- ***General guidance***

- **CombatCOVID official website:** <https://combatcovid.hhs.gov/>
- **mAb product locator tool:** <https://protect-public.hhs.gov/pages/therapeutics-distribution/>
- **Bamlanivimab FAQ:** <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/bamlanivimab-faq.aspx>
- **Casirivimab + Imdevimab FAQ:** [https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas\\_imd/Pages/faq.aspx](https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/faq.aspx)
- **FAQ for non-hospital sites:** <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/FAQs-mAB.aspx>
- **mAb Infusion Center Model:** <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Monoclonal-Antibody-Infusion-Center-Model-508.pdf>

## Tools/Resources (cont.)

- ***More information***

- **HHS / ASPR Office Hours (Tue 1-1:30PM EST, Thu 2-2:30PM EST)**

- Open forum for state and territorial health officer, health care providers and sties of care to reach out on questions for administration of therapies
- Contact [ASPRstakeholder@hhs.gov](mailto:ASPRstakeholder@hhs.gov) for inclusion

- **ECHO – Outpatient Therapeutics Mini-Series (Wed 12-1PM EST)** for clinical overview and examples of administration models

- <https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html>

- **Regional Emergency Coordinators:**

<https://www.phe.gov/Preparedness/responders/rec/Pages/default.aspx>

Questions?





**Thank you!**