

Access the entire webinar series here:

<https://files.asprtracie.hhs.gov/documents/aspr-tracie-healthcare-operations-during-covid-19-pandemic-webinar-series.pdf>

Access the speaker bio here:

<https://files.asprtracie.hhs.gov/documents/healthcare-operations-speaker-series-speed-speaker-bio.pdf>

Access this webinar here:

<https://attendee.gotowebinar.com/recording/8801899956547851536>



T R A C I E
HEALTHCARE EMERGENCY PREPAREDNESS
INFORMATION GATEWAY

Healthcare Operations during the COVID-19 Pandemic- Speaker Series

March 2021

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SPEED

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

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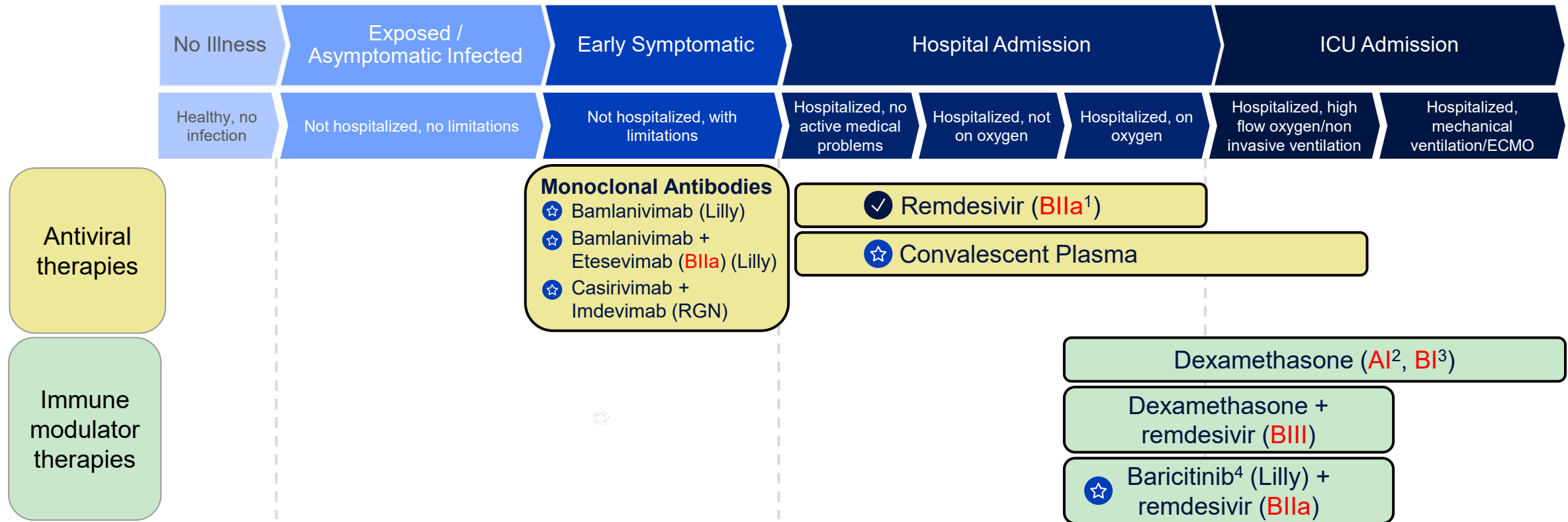
Lead SPEED Program, COVID-19 Response Therapeutics Team

MARCH 5, 2021

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Overview of therapeutic options to treat COVID-19

Summary of COVID-19 Therapeutics: 8 products with FDA approval or EUA; 5 products recommended in NIH guidelines



Note: Ratings in red represent NIH treatment guideline recommendations
Rating of Recommendations: A = strong; B = moderate; C = optional
Rating of Evidence: I = one or more randomized trials without major limitations; IIa = other randomized trials or subgroup analyses of randomized trials; IIb = nonrandomized trials or observational cohort studies; III = expert opinion

Key: ✓ FDA approved ★ EUA issued

Note: Continuous renal replacement therapy (CRRT) systems (from Baxter and Fresenius) and Propoven have also received EUAs; not included above as they are outside the Operation's mission 1. BIIa rating only applicable for patients who require minimal supplemental oxygen; insufficient data for use in patients without oxygen requirement; 2. A1 rating for patients requiring invasive mechanical ventilation or ECMO; 3. BI rating for hospitalized requiring supplemental oxygen; 4. In the rare circumstance corticosteroids cannot be used, baricitinib + remdesivir can be used Source: NIH COVID-19 Treatment Guidelines, "Therapeutic Management of Adults with COVID-19"; UpToDate.com, "Coronavirus disease 2019 (COVID-19): Management in hospitalized adults"

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

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

<https://combatcovid.hhs.gov/>

SPEED Program

SPEED Overview

- Established mid-December 2020
- Facilitated 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
- Provided direct allocation, targeted outreach and engagement with priority sites
- Developed partnerships with stakeholder and trade associations
- SPEED Website:
<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx>

SPEED Keys to Success

- Partnerships with associations
 - Rapidly recruit and educate participating sites
 - Quickly understand sector landscape
 - Efficiently disseminate information and collect data
- Engagement with sites
 - Answered questions
 - Bolstered confidence
 - Confirmed capability
 - Shared key resources

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 instructions:

- Name of Requestor ***: A text input field.
- Requestor Email ***: A text input field.
- Urgent? (Y*)**: A text input field. Below it, instructions state: "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." Below this is another text input field.
- Prior C19 Receipt? ***: A dropdown menu. Below it, instructions state: "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 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.

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 quantity **used in the last week** 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>

Long Term Care Facilities

LTCF Partners

- Partners include:
 - [National Home Infusion Association](#)
 - [American Society of Consultant Pharmacists](#)
 - [AMDA – The Society for Post-Acute and Long-Term Care Medicine](#)
 - Argentum
 - LeadingAge
 - American Health Care Association – National Center for Assisted Living
- Membership in partner associations is not required for participation in SPEED

LTC Pharmacies & Home Infusion Centers Participating in SPEED

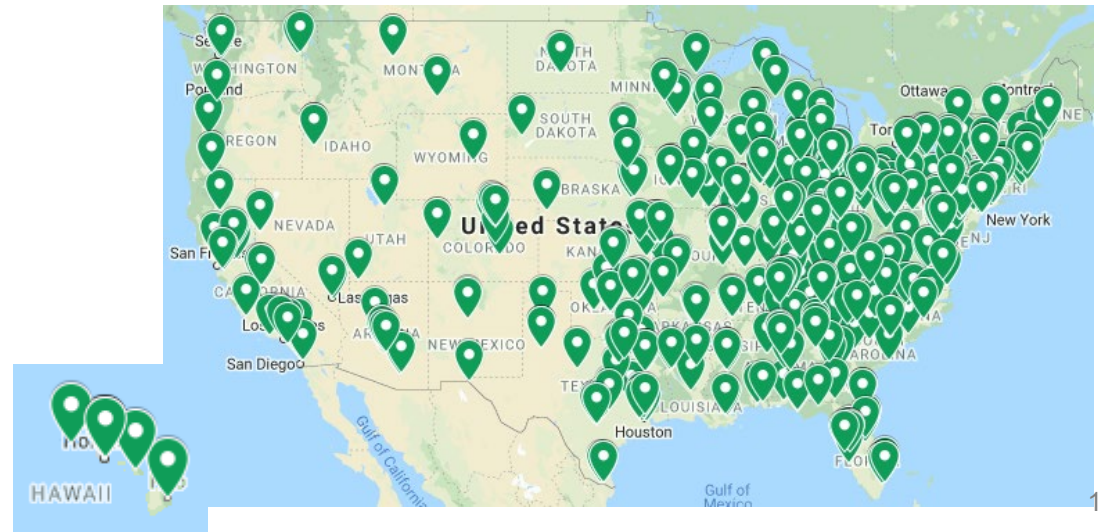
To date, **172 Home Infusion Centers** and **521 Long Term Care Pharmacies** – representing 49 states – are participating in SPEED

To date:

- **23,424** patient courses of **bamlanivimab** and **6** patient courses of **casirivimab/imdevimab** have been distributed to LTC Pharmacies
- **3,466** patient courses of **bamlanivimab** and **1** patient course of **casirivimab/imdevimab** have been distributed to home infusion providers



Home Infusion Centers



LTC Pharmacies

Dialysis Centers

Dialysis Partners

- Association partners include:
 - American Society of Nephrology
 - ESRD Networks
 - Kidney Community Emergency Response
 - Renal Healthcare Association
- Dialysis Companies:
 - DaVita Kidney Care
 - Fresenius Kidney Care
 - U.S. Renal Care
- State Departments of Health

Dialysis Centers Participating in SPEED

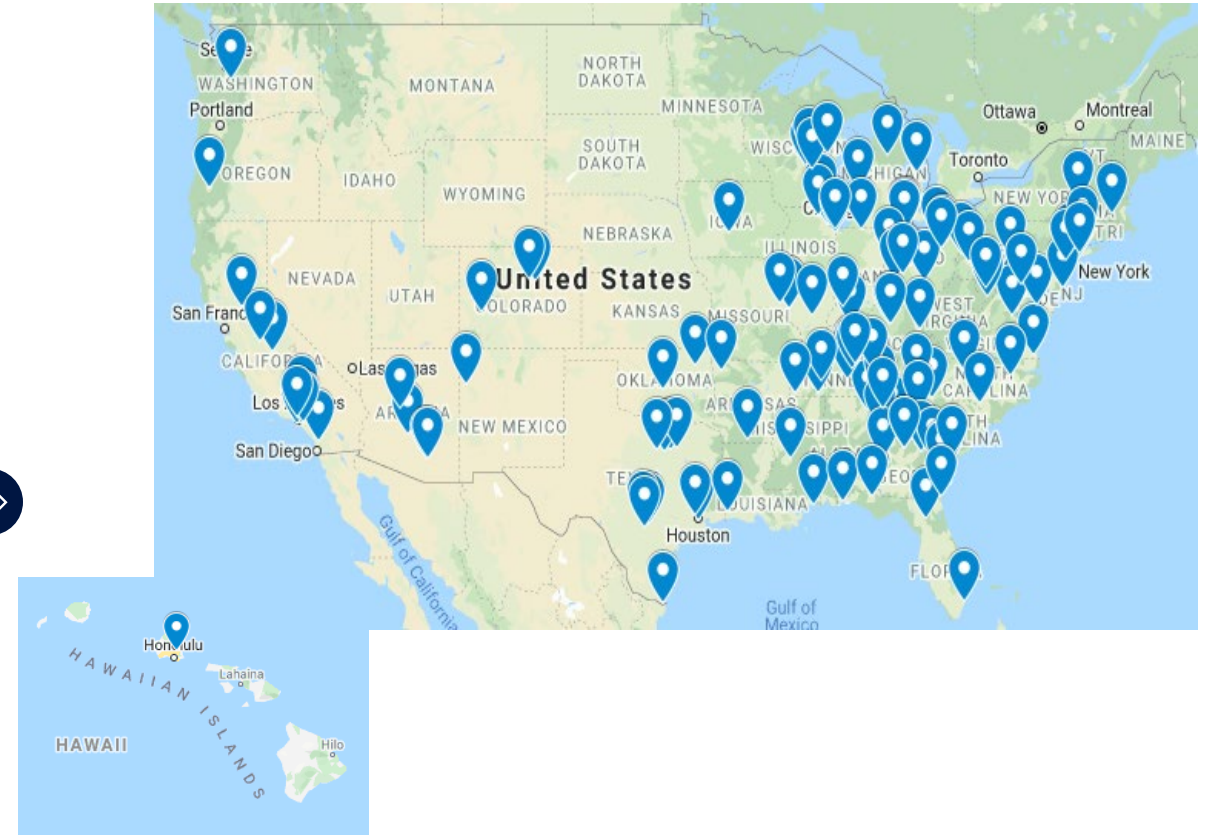
To date, **1,101 facilities** – across 44 states – are participating in SPEED

Variety among participants:

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

To date:

- **3,078** patient courses of **bamlanivimab** and **6** patient courses of **casirivimab/imdevimab** have been distributed to Dialysis Centers



FQHCs

FQHC Partners

- National Association of Community Health Centers
- State Primary Care Associations and Regional Leadership
- Emergency Management Advisory Coalition
- HRSA Bureau of Primary Care
- State Departments of Health

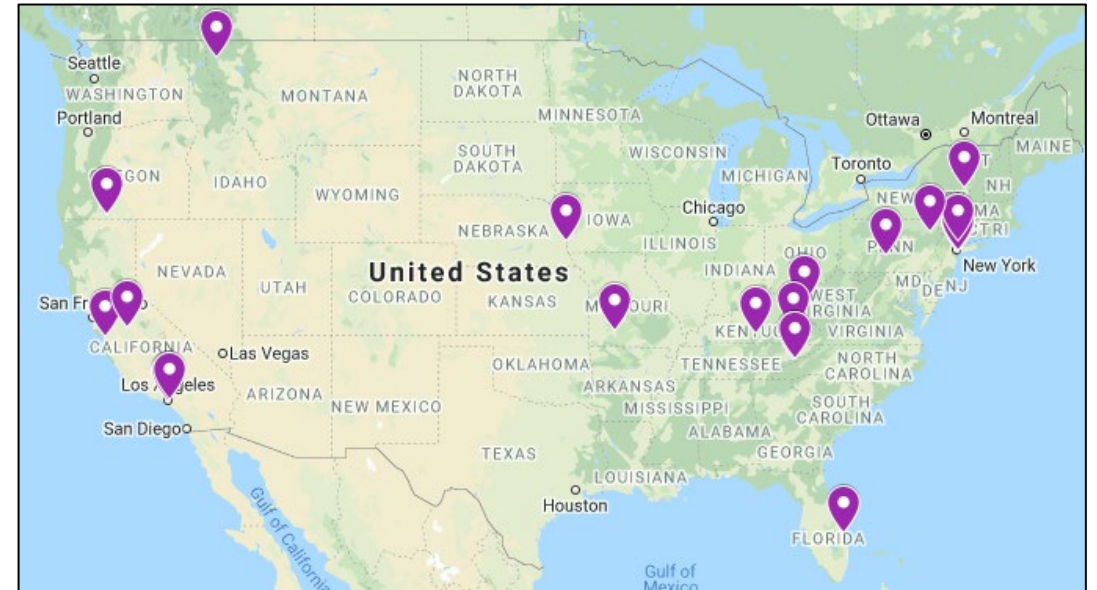
FQHCs Participating in SPEED

To date, **24 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



More on FQHCs

- Administration models
 - On-site administration (coupled with on-site testing)
 - Mobile units
 - Community partners (hospital, infusion center)
 - Drive-up units
 - Others
- Patient education and assistance

Correctional Facilities

Correctional Facility Partners

- State Departments of Health
- State Departments of Correction
- Correctional Healthcare Contractors
- American Correctional Association
- National Institute of Corrections
- National Commission on Correctional Healthcare

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, **five** 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



Future Directions

Future Directions for Equitable Access and Utilization

- Continued engagements with existing partners and sites
- Identifying new partners that represent other vulnerable populations
- Collaborating with other Federal partners
- Working with COVID-19 Health Equity Task Force

SPEED Contact Information and Resources

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
- ***Administration playbooks***
 - **Federal Response mAb Playbook:** 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-mono-clonal-antibodies>
- **HRSA FAQs for COVID-19 Claims Reimbursement:** <https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions>

- ***General guidance***

- **HHS/ASPR Website:** <https://www.phe.gov/>
- **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
- **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/Mono-clonal-Antibody-Infusion-Center-Model-508.pdf>

Tools/Resources (cont.)

- ***More information***

- **HHS / ASPR Office Call Sessions (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

- <https://hhsasproea.zoomgov.com/j/1604329034?pwd=dGRwZTBETTJzWFliQW83TXZSOFVNQT09>

- Meeting ID: 160 432 9034

- Passcode: 897674

- **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>

- **Contact:** COVID19Therapeutics@hhs.gov



Thank you!

Contact ASPR TRACIE

- [ASPR TRACIE COVID-19 Resources](#)
- [ASPR TRACIE Planning Considerations for Monoclonal Antibody Administration](#)



asprtracie.hhs.gov



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