Access the entire webinar series here:

Access the speaker bio here:

Access this webinar here:
https://attendee.gotowebinar.com/recording/8801899956547851536

Healthcare Operations during the COVID-19 Pandemic- Speaker Series

March 2021
SPEED
Special Projects for Equitable and Efficient Distribution of COVID-19 Outpatient Therapeutics

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MARCH 5, 2021
Unclassified//For Public Use
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

No Illness
- Exposed / Asymptomatic Infected
  - Early Symptomatic
    - Not hospitalized, with limitations
    - Hospitalized, no active medical problems
    - Hospitalized, not on oxygen
    - Hospitalized, on oxygen
    - Hospitalized, high flow oxygen/non invasive ventilation
    - Hospitalized, mechanical ventilation/ECMO

Healthy, no infection
- Not hospitalized, no limitations
- Not hospitalized, with limitations
- Hospitalized, no active medical problems
- Hospitalized, not on oxygen
- Hospitalized, on oxygen
- Hospitalized, high flow oxygen/non invasive ventilation
- Hospitalized, mechanical ventilation/ECMO

Monoclonal Antibodies
- Bamlanivimab (Lilly)
- Bamlanivimab + Etesevimab (BIIa) (Lilly)
- Casirivimab + Imdevimab (RGN)

Remdesivir (BIIa)

Convalescent Plasma

Dexamethasone (AI², BI³)

Dexamethasone + remdesivir (BIIa)

Baricitinib⁴ (Lilly) + remdesivir (BIIa)

Key: ✔️ FDA approved ⭐ EUA issued

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; Ila = other randomized trials or subgroup analyses of randomized trials; IIb = nonrandomized trials or observational cohort studies; III = expert opinion
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:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
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<tbody>
<tr>
<td>Have BMI ≥ 35</td>
<td></td>
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<tr>
<td>Have chronic kidney disease</td>
<td></td>
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<tr>
<td>Have diabetes</td>
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<tr>
<td>Have immunosuppressive disease</td>
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<tr>
<td>Are currently receiving immunosuppressive treatment</td>
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<tr>
<td>Are ≥ 65 years of age</td>
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<tr>
<td>Are ≥ 55 years of age AND have</td>
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<tr>
<td>- Cardiovascular disease, OR</td>
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<td>- Hypertension, OR</td>
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<tr>
<td>- Chronic obstructive pulmonary disease (or others)</td>
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<tr>
<td>Are 12-17 years of age AND have</td>
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<tr>
<td>- BMI ≥ 85th percentile for age/gender based on CDC growth charts, OR</td>
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<td>- Sickle cell disease, OR</td>
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<td>- Congenital or acquired heart disease, OR</td>
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<td>- Neurodevelopmental disorders, OR</td>
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<td>- A medical-related technological dependence, OR</td>
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<tr>
<td>- Asthma, reactive airway or other chronic resp. disease that requires daily meds/control</td>
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</table>

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/](https://combatcovid.hhs.gov/)
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

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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

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](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
• 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 fulfillment 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.

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:
Long Term Care Facilities
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.
Dialysis Centers
• 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

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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](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**
Tools/Resources (cont.)

• **Reimbursement information**
  • 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/Monoclonal-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 sites of care to
      reach out on questions for administration of therapies
    • https://hhsasproea.zoomgov.com/j/1604329034?pwd=dGRwZTBETJzWFliQW83TXZSOFVNQT09
    • Meeting ID: 160 432 9034
    • Passcode: 897674
  • ECHO – Outpatient Therapeutics Mini-Series (Wed 12-1PM EST) for clinical
    overview and examples of administration models
  • 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  1-844-5-TRACIE  askasprtracie@hhs.gov