Presented by:

HAH Healthcare Association of Hawaii

HHERF Hawaii Hospital Education and Research Foundation

Hawaii Medical Directors Association
Society for Post-Acute & Long-Term Care Medicine.

HMDA

Welcome to

Keep Educating Yourself

The Critical Role of Monoclonal Antibodies as the COVID-19 Pandemic Continues

Speaker:
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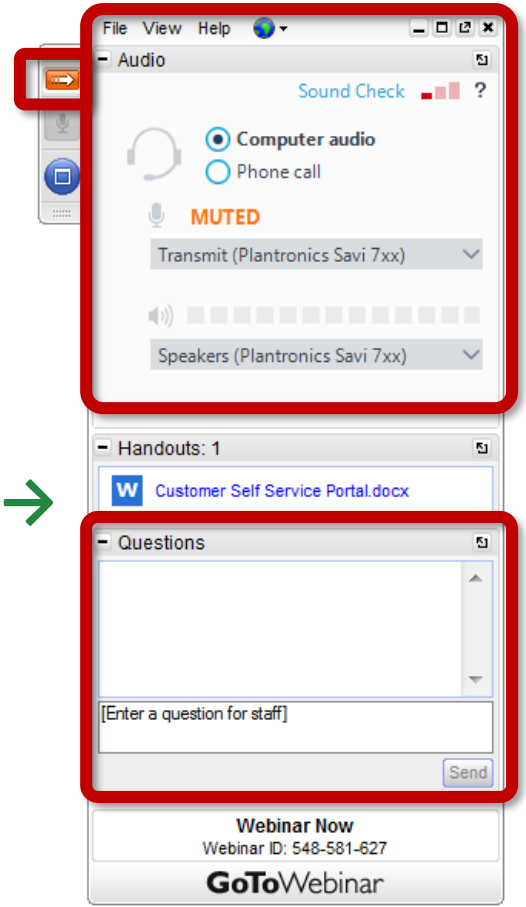
Panelists:
Gina Smith, RN, CHEP, NHDP-BC
Kiersten Henry, DNP, ACNP-BC

August 26, 2021
9:00 - 10:00 am HST



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Join audio:

- Choose "Computer audio" to use VoIP or
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Questions/Comments:

- Submit questions and comments via the Questions panel.

Note: Today's presentation is being recorded. The on-demand recording will be available within one week of the live webinar at https://www.hah.org/protected-82621-hhs-mabs-ondemand-links

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COVID-19 Monoclonal Antibody Therapeutics: Drug Distribution and Administration

John T. Redd, MD, MPH, FACP CAPT, U.S. Public Health Service
Chief Medical Officer, U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response

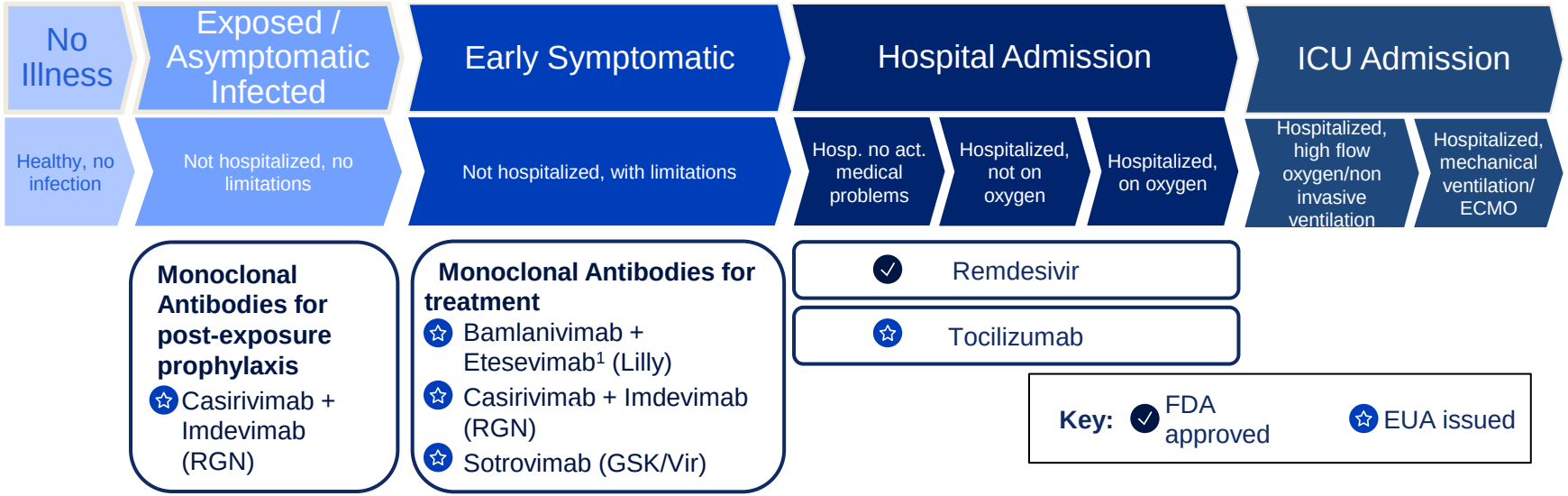
August 26th, 2021

Agenda

- MAb Introduction
- EUA Changes and Updates
- Variants
- Data
- Strategies to increase uptake

Introduction to mAb therapies

Summary of COVID-19 Therapeutics



1. National shipment pause due to variants, as of 06/25/2021

Bottom Line: monoclonal antibodies for treatment reduce relative risk of hospitalization

- COVID-19 monoclonal antibodies (mAbs) are intended for individuals with **mild to moderate COVID-19 who are at high-risk of developing severe disease**
- mAbs are likely to be most effective when **given early in disease course**
- Early evidence appears to suggest promise of mAb products in outpatient settings; products (bamlanivimab and etesevimab[1] together and REGEN-COV (casirivimab and imdevimab)) **reduce the relative risk of hospitalizations by up to 70% in high-risk patients**

1. National shipment pause due to variants, as of 06/25/2021

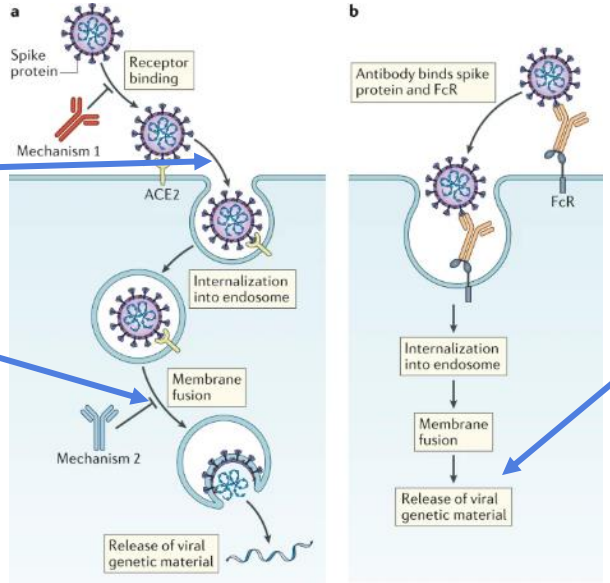
Potential mechanisms for the clinical effects of monoclonals

a) Bind to Virus

1) Block cell uptake

2) Block membrane fusion

Impede ability to replicate



b) Bind to Virus

3) Deliver to immune

Destruction

Source: Nature

USG role in distribution of COVID-19 mAbs

Our goal: Facilitate the effective use of mAbs to reduce COVID-19 hospitalizations

Three outpatient mAbs have been granted EUA for the treatment of COVID-19 based on their potential to reduce progression to severe disease and hospitalization in high-risk patients:

- **Post-exposure prophylaxis**
  - REGEN-COV (casirivimab and imdevimab)

- **Active COVID-19 infection in high-risk individuals** with mild to moderate symptoms
  - REGEN-COV (casirivimab and imdevimab)
  - Bamlanivimab and etesevimab (together) (currently paused[1])
  - Sotrovimab (commercially available)

HHS/ASPR has oversight responsibility for the fair and transparent allocation and distribution of REGEN-COV and bamlanivimab and etesevimab (together)

1. National shipment pause of bam / ete and ete alone due to variants, as of 06/25/2021

Updates Aug 2021

EUA Updates

Therapy	EUA Issuance	EUA revisions	USG procured?
Bamlanivimab *(Eli Lilly & Co.)*	Nov. 9, 2020	EUA revoked – April 16, 2021 • Due to sustained increase of viral variants resistant to bamlanivimab alone	Yes
REGEN-COV (casirivimab and Imdevimab) *(Regeneron)*	Nov. 21, 2020 (treatment) Jul. 30, 2021 (post-exposure prophylaxis)	EUA revised – 03/2021 • Antiviral resistance EUA revised – 05/2021 • **Updated high risk criteria** for patient selection EUA revised – 06/2021 • Updated w/ coformulation • Updated w/ **subcutaneous RoA** as an alternative to IV • Updated authorized dosage EUA revised – 07/2021 • Updated authorized **use for post-exposure prophylaxis**	Yes
Bamlanivimab and Etesevimab[1] (together) *(Eli Lilly & Co.)*	Feb. 9, 2021	EUA revised – 05/2021 • Updated high risk criteria for patient selection • Antiviral resistance	Yes
Sotrovimab *(GSK / Vir Biotechnology)*	May 26, 2021	N/A	No, commercially available

1. National shipment pause due to variants, as of 06/25/2021

1) mAb treatment eligibility

- May be eligible to receive treatment if the patient (12 years of age or older and weighing at least 40 kg):
  - Has mild to moderate COVID-19 that has tested positive with direct viral testing,
  - Is within 10 days of symptom onset, **and**
  - Is at high risk of progression to severe COVID-19 including hospitalization or death

- Please reference EUA factsheets for specific treatment guidelines and detailed definitions of high-risk patients
  - Bamlanivimab and etesevimab[1] (together)
  - REGEN-COV (casirivimab and Imdevimab)

1. National shipment pause due to variants, as of 06/25/2021

2) EUA for REGEN-COV™ (casirivimab and imdevimab) treatment

- Effective June 3, 2021, the FDA has authorized under emergency use a **lower dose** of REGEN-COV (600mg casirivimab and 600mg imdevimab), which is half the dose originally authorized
- REGEN-COV should be administered by intravenous (IV) infusion; subcutaneous injections are an **alternative when IV infusion is not feasible** and would lead to a delay in treatment
- **Single vial of co-formulated product now available to order via AmerisourceBergen (as of June 10, 2021)**
  - Single vial represents one full, complete treatment at the lower authorized dose

Please contact Regeneron Medical Affairs with any questions about using **existing** inventory to treat patients at 1-844-734-6643

3) FDA authorizes Sotrovimab for treatment of COVID-19

- Effective May 26, 2021**, Sotrovimab (GSK / Vir Biotechnology) authorized for the treatment of mild to moderate COVID-19**
- Commercially available therapy
- Please refer to the following for more information:
  - FDA fact sheet and EUA Letter of authorization
  - FDA press release
  - COMET-ICE clinical trial
- For additional information and approved materials, **including information about ordering**, please refer to the Sotrovimab webpage

Please contact the GSK COVID Contact Center if you have further questions:

1-866-GSK-COVID (1-866-475-2684)

4) COVID-19 treatment guidelines

- The COVID-19 Treatment Guidelines Panel **recommends** using one of the following anti-SARS-CoV-2 monoclonal antibodies, to treat non-hospitalized patients with mild to moderate COVID-19 who are at high risk of clinical progression:
  - **Casirivimab 600 mg plus imdevimab 600 mg IV infusion (AIIa)**; or
    - If IV infusions are not feasible or would cause a delay in treatment, **casirivimab 600 mg plus imdevimab 600 mg** administered by four subcutaneous (SQ) injections can be used as an alternative **(BIII)**
  - **Sotrovimab 500 mg intravenous (IV) infusion**
- Treatment w/ mAbs should be started as soon as possible after the patient receives a **positive result** and **within 10 days of symptom onset**
- The use of bamlanivimab plus etesevimab (AIII)[1] is not recommended because the Gamma (P.1) and Beta (B.1.351) variants, which have reduced susceptibility to both agents, are circulating in the U.S.

1. National shipment pause due to variants, as of 06/25/2021

Ratings of NIH treatment guidelines 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

2

mAbs for post-exposure prophylaxis use-case updates

REGEN-COV Emergency Use Authorization (EUA) expanded to include post-exposure prophylaxis

- As of July 30, 2021, **FDA has authorized post-exposure prophylaxis use of the COVID-19 monoclonal antibody therapeutic REGEN-COV (casirivimab and imdevimab) for eligible, high-risk individuals**
- REGEN-COV is expected to be effective against circulating variants, including the Delta variant. Please refer to the following for more information:
  - FDA fact sheet and EUA Letter of authorization
  - Regeneron press release
- For additional information and approved materials, including information about ordering, please refer to the REGEN-COV webpage
- Should you have any questions regarding the expanded indication for REGEN-COV, please contact us at COVID19Therapeutics@hhs.gov

REGEN-COV post-exposure prophylaxis treatment eligibility

REGEN-COV (casirivimab and imdevimab) is authorized for post-exposure prophylaxis of COVID-19:

- ***in adult and pediatric individuals*** (≥12 yrs+, weighing ≥40 kg) who are at ***high risk for progression to severe COVID-19***, including hospitalization or death, ***and*** are:
- ***Not fully vaccinated or who are not expected to mount an adequate immune response*** to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) ***and***
  - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC ***or***
  - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

New authorized use is in addition to the prior authorization of REGEN-COV to treat

- **non-hospitalized patients w/ mild to moderate COVID-19** in adult and pediatric patients, aged 12 and older, w/ **positive results** of direct SARS-CoV-2 viral testing, and who are **at high risk** for progression to severe COVID-19

Limitations of authorized use:

- *Post-exposure prophylaxis w/ REGEN-COV is not a substitute for vaccination against COVID-19*
- *REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19*

Guidelines for REGEN-COV repeat dosing for post-exposure prophylaxis

- For individuals whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination
- Initial dose is 600 mg of casirivimab + 600 mg of imdevimab by subcutaneous injection or intravenous infusion
- Followed by subsequent repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by subcutaneous injection or intravenous infusion **once every 4 weeks** for the duration of ongoing exposure

Indications for Monoclonal Therapy & Appropriate mAbs for Treatment

- Post-Exposure Prophylaxis in vulnerable persons (i.e. not fully vaccinated or immunocompromised) who are at high risk for progression to severe COVID-19
  - REGEN-COV (casirivimab and imdevimab)
- Active COVID-19 Infection in high risk individuals with mild to moderate symptoms
  - REGEN-COV (casirivimab and imdevimab)
  - Bamlanivimab/Etesevimab (currently paused)
  - Sotrovimab (commercially available)

Pre-approval, not for distribution 7_29_21

Eligibility for Post-Exposure Prophylaxis**

Same as slide 16. Consider removing

- REGEN-COV (casirivimab and imdevimab) is authorized for for post-exposure prophylaxis of COVID-19 in individuals who are:
  - Adult or pediatric (≥ 12 years of age and weighing at least 40kg) patient **at high risk for progressing to severe disease or death**
  - Not fully vaccinated[1] **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications[2]) **AND**
    - ✓ have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC[3] **OR**
    - ✓ **who are at high risk of exposure to an individual infected with SARS-CoV-2** because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons) [*see limitations of authorized use]*

***Limitations of Authorized Use:**

- *Post-exposure prophylaxis with REGEN-COV (casirivimab and imdevimab) is not a substitute for vaccination against COVID-19*
- *REGEN-COV (casirivimab and imdevimab) is not authorized for pre-exposure prophylaxis for prevention of COVID-19*

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html#vaccinated
[2] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html
[3] https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html

Eligibility for Post-Exposure Prophylaxis

- [1] Individuals are considered to be **fully vaccinated** 2 weeks after their second vaccine dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as Johnson & Johnson's Janssen vaccine). See this website for more details: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html#vaccinated
- [2] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html
- [3] **Close contact** with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). See this website for additional details: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html

HIGH RISK FACTORS INCLUDE, BUT ARE NOT LIMITED TO:

- Older age (for example ≥ 65 years of age)
- Obesity or being overweight (for example, adults with BMI ≥ 25, or if age 12-17, have BMI ≥ 85th percentile for their age and gender based on CDC growth charts)
- Pregnancy
- Chronic Kidney Disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital abnormalities)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and **authorization of mAb therapy is not limited to the medical conditions or factors listed above**. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, visit the CDC website:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

https://www.cdc.gov/growthcharts/clinical_charts.htm

Same as slide 17. Consider removing

Guidelines for REGEN-COV Repeat Dosing for Post-Exposure Prophylaxis ★

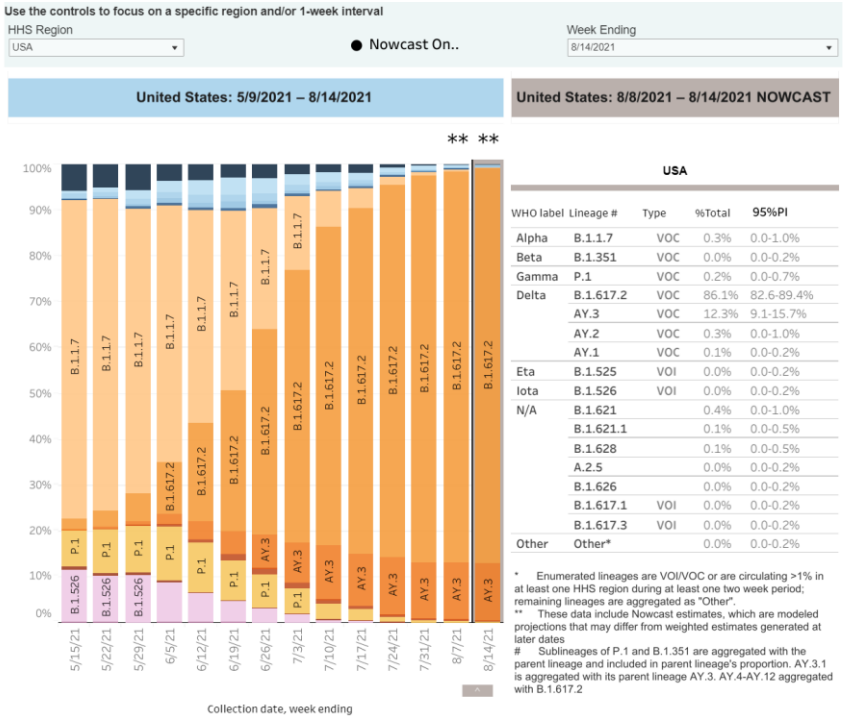
- For individuals whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination

- The initial dose is 600 mg of casirivimab and 600 mg of imdevimab by subcutaneous injection or intravenous infusion

- Followed by subsequent repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by subcutaneous injection or intravenous infusion once every 4 weeks for the duration of ongoing exposure.

Variants

Presence of Delta variant nationally



USA

WHO label	Lineage #	Type	%Total	95%PI
Alpha	B.1.1.7	VOC	0.3%	0.0-1.0%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	0.2%	0.0-0.7%
Delta	B.1.617.2	VOC	86.1%	82.6-89.4%
	AY.3	VOC	12.3%	9.1-15.7%
	AY.2	VOC	0.3%	0.0-1.0%
	AY.1	VOC	0.1%	0.0-0.2%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.0%	0.0-0.2%
N/A	B.1.621		0.4%	0.0-1.0%
	B.1.621.1		0.1%	0.0-0.5%
	B.1.628		0.1%	0.0-0.5%
	A.2.5		0.0%	0.0-0.2%
	B.1.626		0.0%	0.0-0.2%
	B.1.617.1	VOI	0.0%	0.0-0.2%
	B.1.617.3	VOI	0.0%	0.0-0.2%
Other	Other*		0.0%	0.0-0.2%

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Sublineages of P.1 and B.1.351 are aggregated with the parent lineage and included in parent lineage's proportion. AY.3.1 is aggregated with its parent lineage AY.3. AY.4-AY.12 aggregated with B.1.617.2

- Delta (B.1.617.2) variant was at 31% nationally as of 6/19 and is **86.1% nationally as of 8/14** (pending data via Nowcast)
- States/territories encouraged to reach out with questions/concerns

National shipment pause of bamlanivimab and etesevimab (together) and etesevimab alone due to Beta and Gamma variant prevalence

Presence of variants

- CDC has identified the **combined frequencies of Beta variant (B.1.351,** first identified in South Africa) and **Gamma variant** (**P.1,** first identified in Brazil) **throughout the U.S. has been trending upward**
- Results from in vitro studies suggest that:
  - Bamlanivimab and etesevimab (together) administered together **are not active against** either Beta (B.1.351) or Gamma (P.1) variants
  - REGEN-COV and sotrovimab **are likely to retain activity** against Beta (B.1.351) and Gamma (P.1) variants

Impact on providers

- Effective as of 06/25/2021, **distribution of bam / ete together and etesevimab alone have been paused on a national basis until further notice**
- **FDA recommends health care providers use alternative authorized mAb therapies** (REGEN-COV or sotrovimab) until further notice
  - REGEN-COV can be ordered directly from Amerisource Bergen
  - Sotrovimab can be ordered via GlaxoSmithKline's website

Please contact **COVID19Therapeutics@hhs.gov** with any questions

Clinical Data

Review of clinical data (I/II)

Date	Source	Trial design / patients	Reported outcomes	Notes
Jan 2021	JAMA	RCT, n = 577	▪ 70% reduction in hospitalization for high-risk patients	Lillly trial (Ph 2)
Feb 2021	Website	Observational	▪ 50% decrease in hospitalizations, 40% decrease in emergency department visits	St. Luke's
Mar 2021	Lily	RCT, n = 769	▪ 87% relative reduction vs. placebo in hospitalizations / death	Lilly trial (Ph 3)
Mar 2021	Regeneron	RCT, n = 4,567	▪ 70% relative reduction vs. placebo in hospitalizations / death	Regen. trial (Ph 3)
Mar 2021	NEJM	Observational, n not listed	▪ 4.2% hospitalization rate for those treated with mAbs vs. 9-14.6% reported for untreated high-risk ▪ Only 13% felt symptoms progressed after therapy	Houston Methodist
Mar 2021	Medrxiv	Observational, n = 234 matched,	▪ Patients receiving mAb had 69% lower odds of hospitalization or mortality, and 50% lower odds of hospitalization or ED visit without hospitalization ▪ 6% hospitalization in treated vs. 16.2% untreated,	UPMC
Apr 2021	Medrxiv	Observational, n = 270 treated, 328 untreated	▪ 1.9% of treated patients presented to E.D. / required hospitalization vs. 12% of untreated	ASPR

Review of clinical data (II/II)

Date	Source	Trial design / patients	Reported outcomes	Notes
Apr 2021	Medrxiv	Observational, n = 2,818	▪ Hospitalization rate was 4.4% for patients who received MAB therapy w/in 0-4 days, 5% w/in 5-7 days, and 6.1% w/in ≥8 days of symptom onset (p = 0.15)	Northwell Health
May 2021	Medrxiv *(preprint)*	RCT, n = 4,057	▪ 2400mg & 1200mg drugs sig. reduced hospitalization or all-cause death compared to placebo (71.3% reduction [1.3% vs 4.6%; p<0.0001] and 70.4% reduction [1.0% vs 3.2%; p=0.0024], respectively	Regen. trial
Jun 2021	JAMA	RCT, n = 1175	▪ Bam significantly reduced the incidence of COVID-19 in the prevention population compared with placebo (p<.001) at skilled nursing/assisted living facilities	Lilly trial (Ph 3)
Aug 2021	NEJM	RCT, n = 2475	▪ Subcutaneous REGEN-COV prevented symptomatic Covid-19 and asymptomatic SARS-CoV-2 infection in previously uninfected household contacts of infected persons (p<0.001) ▪ Among participants who became infected, REGEN-COV reduced duration of symptomatic disease and high viral load (p<0.001)	Regen. trial

COVID-19 Monoclonal Antibody (mAb) Therapy Real-World Effectiveness and Implementation

Date	Source	Article	Description
Mar '21	NEJM	*Rapid operationalization of COVID-19 mAb infusion clinics at Houston Methodist*	• Established six clinics in <6 weeks across Houston region - Treated 2,500+ high-risk patients w/ mAb Tx - Avoided ~250 COVID-19–related hospitalizations • Patient experience: - Nearly 99% of patients would recommend the treatment - 95% of patients confident in comms b/w providers
May '21	UPMC	*UPMC and HHS Leaders Discuss Expanded Eligibility Guidelines for Life-Saving COVID-19 Treatment*	• UPMC saw a 25-fold inc. in the administration of mAb treatments since March

Strategies to increase uptake

USG-procured therapies are provided at no-cost

- Health care providers can order product directly through the distributor AmerisourceBergen at no cost; information on ordering available at PHE.gov
- CMS reimbursement rates have recently been increased to $450 for most outpatient settings; and $750 when administered in a patient's home
- Additional information on reimbursement can be found at Monoclonal Antibody COVID-19 Infusion | CMS
- Treatment options for uninsured individuals available through HRSA

USG activities to support administration of mAbs

1. **Build product understanding and awareness** – Ensure **providers are up-to-date** on the **latest EUA therapies** (and eligible patient populations), and **patients are aware of treatment options**

2. **Provide information on product location** – Ensure providers have the information to **direct patients to a place to receive treatment**

3. **Facilitate product administration** – Ensure providers can **safely administer current products** (drug on hand, material, directions, etc.)

4. **Track utilization** – **Understand utilization of product** across localities and populations

Administration can occur across a wide variety of models

Hospital

- Hospital-based infusion centers
- Emergency departments
- Converted space within hospital for COVID infusion
- Alternate care sites

Ambulatory center

- Infusion centers
- Urgent care clinics
- Dialysis centers
- Alternate care sites

Nursing homes

- Skilled nursing facilities
- Long-term care facilities

Mobile sites

- Bus/trailer
- Other mobile sites

Home

- At patient's home

Information support via PHE.gov/mAbs and CombatCOVID.hhs.gov/
Materials include links to EUA criteria, consolidated playbooks & educational materials

mAb expansion efforts

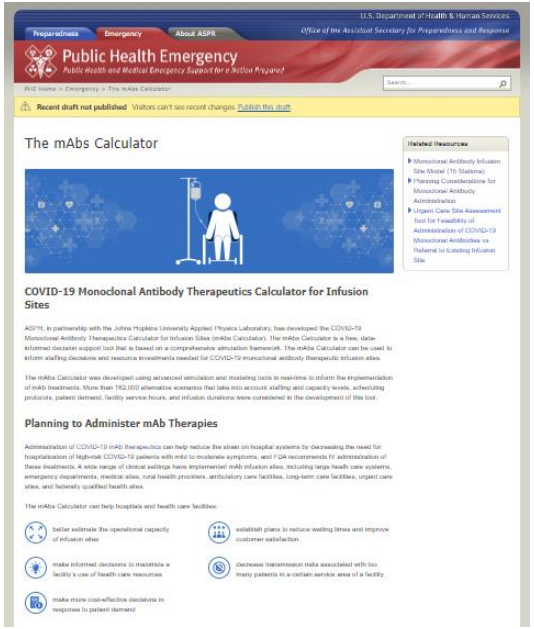
- **Expansion of capacity** in existing care sites with or without current infusion capabilities
- Setup of **new temporary capacity** (e.g., “pop-up” centers, mobile units, tents, etc.)
- Setup of **new “semi-permanent” capacity** (e.g., new brick & mortar locations)
- **Virtual support** for existing / new centers (e.g., IT support, administrative support, education & training for staff, telemedicine screeners and follow-up, etc.)
- **Staff support** for infusions in congregate settings (e.g., long-term care facilities)
- **Infusion site access** to not just the general public, but to military and their dependents
- **Increased provider and patient awareness** about mAbs and opportunities for use

mAb calculator now live on phe.gov

COVID-19 monoclonal antibody therapeutics calculator for infusion sites

mAbs Calculator can help hospitals and health care facilities:

- Better estimate the **operational capacity of infusion sites**
- Make informed decisions to **maximize a facility's use of health care resources**
- Make more **cost-effective decisions in response to patient demand**
- **Establish plans to reduce waiting times** and **improve customer satisfaction**
- **Decrease transmission risks** associated with too many patients in a certain service area of a facility



Learn More at www.PHE.gov/mAbs-calculator

Best practices and resources

- USG engages with medical and professional societies to share best practices
- Best practices and testimonials available at https://combatcovid.hhs.gov/hcp/videos-monoclonal-antibodies
- Additional information and resources available at PHE.gov/mAbs and CombatCOVID.hhs.gov

mAb calculator live on phe.gov/mAbs

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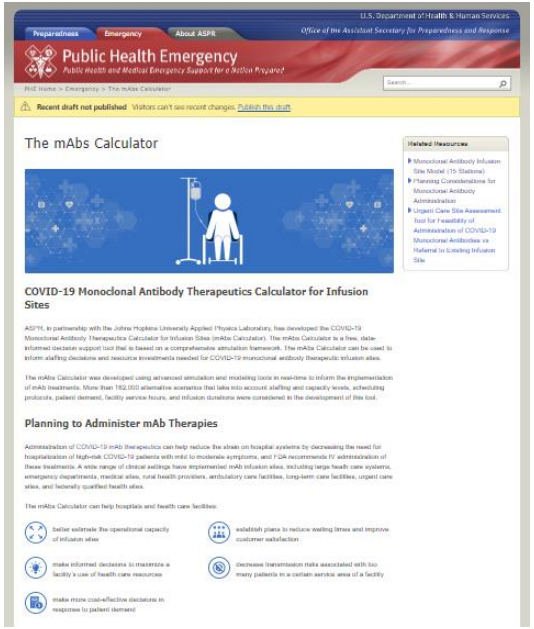
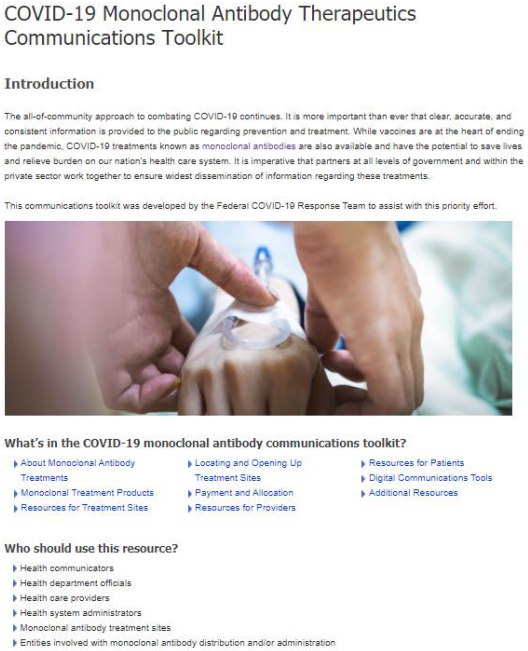


Learn more at www.PHE.gov/mAbs-calculator

Reminder: COVID-19 mAb information toolkit is now live on PHE.gov/mAbs



COVID-19 Monoclonal Antibody Therapeutics Communications Toolkit

Introduction

The all-of-community approach to combating COVID-19 continues. It is more important than ever that clear, accurate, and consistent information is provided to the public regarding prevention and treatment. While vaccines are at the heart of ending the pandemic, COVID-19 treatments known as monoclonal antibodies are also available and have the potential to save lives and relieve burden on our nation's health care system. It is imperative that partners at all levels of government and within the private sector work together to ensure widest dissemination of information regarding these treatments.

This communications toolkit was developed by the Federal COVID-19 Response Team to assist with this priority effort.

What's in the COVID-19 monoclonal antibody communications toolkit?

- About Monoclonal Antibody Treatments
- Monoclonal Treatment Products
- Resources for Treatment Sites
- Locating and Opening Up Treatment Sites
- Payment and Allocation
- Resources for Providers
- Resources for Patients
- Digital Communications Tools
- Additional Resources

Who should use this resource?

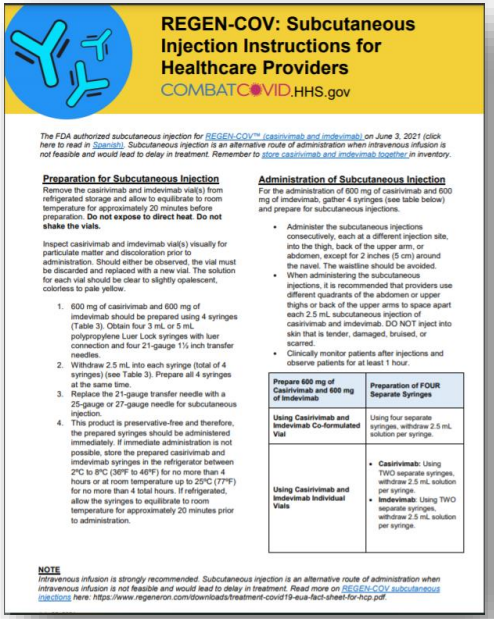
- Health communicators
- Health department officials
- Health care providers
- Health system administrators
- Monoclonal antibody treatment sites
- Entities involved with monoclonal antibody distribution and/or administration

Information toolkit provides a series of resources developed by the Federal COVID-19 response team and other partners on monoclonal antibody therapeutics.

Information resources include content useful for:

- Communicators / Public Information Officers
- Administration sites
- Healthcare providers
- Patients
- Digital media tools

Provider education materials for Post-Exposure Prophylaxis (PEP) administration



REGEN-COV: Subcutaneous Injection Instructions for Healthcare Providers

COMBATCOVID.HHS.gov

The FDA authorized subcutaneous injection for REGEN-COV™ (casirivimab and imdevimab) on June 3, 2021 (click here to read in Spanish). Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment. Remember to store casirivimab and imdevimab together in inventory.

Preparation for Subcutaneous Injection

Remove the casirivimab and imdevimab vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. **Do not expose to direct heat. Do not shake the vials.**

Inspect casirivimab and imdevimab vial(s) visually for particulate matter and discoloration prior to administration. Should either be observed, the vial must be discarded and replaced with a new vial. The solution for each vial should be clear to slightly opalescent, colorless to pale yellow.

1. 600 mg of casirivimab and 600 mg of imdevimab should be prepared using 4 syringes (Table 3). Obtain four 3 mL or 5 mL polypropylene Luer Lock syringes with luer connection and four 21-gauge 1½ inch transfer needles.
2. Withdraw 2.5 mL into each syringe (total of 4 syringes) (see Table 3). Prepare all 4 syringes at the same time.
3. Replace the 21-gauge transfer needle with a 25-gauge or 27-gauge needle for subcutaneous injection.
4. This product is preservative-free and therefore, the prepared syringes should be administered immediately. If immediate administration is not possible, store the prepared casirivimab and imdevimab syringes in the refrigerator between 2°C to 8°C (36°F to 46°F) for no more than 4 hours or at room temperature up to 25°C (77°F) for no more than 4 total hours. If refrigerated, allow the syringes to equilibrate to room temperature for approximately 20 minutes prior to administration.

Administration of Subcutaneous Injection

For the administration of 600 mg of casirivimab and 600 mg of imdevimab, gather 4 syringes (see table below) and prepare for subcutaneous injections.

- Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.
- When administering the subcutaneous injections, it is recommended that providers use different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of casirivimab and imdevimab. DO NOT inject into skin that is tender, damaged, bruised, or scarred.
- Clinically monitor patients after injections and observe patients for at least 1 hour.

Prepare 600 mg of Casirivimab and 600 mg of Imdevimab	Preparation of FOUR Separate Syringes
Using Casirivimab and Imdevimab Co-formulated Vial	Using four separate syringes, withdraw 2.5 mL solution per syringe.
Using Casirivimab and Imdevimab Individual Vials	• **Casirivimab:** Using TWO separate syringes, withdraw 2.5 mL solution per syringe. • **Imdevimab:** Using TWO separate syringes, withdraw 2.5 mL solution per syringe.

NOTE

Intravenous infusion is strongly recommended. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment. Read more on REGEN-COV subcutaneous injections here: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf.

On June 3, 2021, the FDA authorized **subcutaneous injection** for REGEN-COV™ (casirivimab and imdevimab) as an **alternative when IV infusion is not feasible** and would lead to a delay in treatment.

REGEN-COV: Subcutaneous injection instructions for healthcare providers flyer is live on phe.gov.

Weekly Engagements

Weekly mAbs Engagement Sessions

- **Stakeholder Call: State, Local, Tribal, and Territorial Health Officials**: Wednesdays (2:00-2:45PM ET)
- **Stakeholder Call: National Health Care and Medical Orgs and Associations** Wednesdays (3:15-4:00PM ET)
- **Office Call Session**: **HHS / ASPR Distribution and Administration of COVID-19 Therapeutics – call all to open to all with equity in the process** Thursdays (2:00-2:30PM ET)

Please email COVID19Therapeutics@hhs.gov to request Zoom links for these calls

Asks for community leaders

Promote the awareness of therapies in your local communities

- Share information in local community outlets
- Post information online for individuals to understand that mAbs are available treatment options (neighborhood apps, social media, etc)
- Host outreach events

Understand where administration locations are in your local community and encourage individuals to seek out mAb treatment

Share experiences to support others in pursuing treatment

- Post information online (blogs, social media, etc.)
- Share your experience with HHS/ASPR at COVID19Therapeutics@hhs.gov

Healthcare Association of Hawaii

HMDA
Hawaii Medical Directors Association
Society for Post-Acute & Long-Term Care Medicine.

HHERF
Hawaii Hospital Education and Research Foundation

Questions?

Type your questions into the Questions tab of your Control Panel.

Speaker: **John T. Redd, MD, MPH, FACP**
Chief Medical Officer
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

Panelists: **Gina Smith, RN, CHEP, NHDP-BC**
Kiersten Henry, DNP, ACNP-BC

www.hah.org

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Hawaii Hospital Education and Research Foundation

On behalf of the Healthcare Association of Hawaii and the Hawaii Medical Directors Association, thank you for attending today's webinar:

The Critical Role of Monoclonal Antibodies as the COVID-19 Pandemic Continues

Evaluation:
https://www.surveymonkey.com/r/JBCH6B8

Please share your feedback with us. Your comments enable us to better plan and execute educational sessions that meet your needs.

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