



Update: Distribution and Administration of COVID-19 Therapeutics

OCTOBER 13, 2021

Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

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Agenda

- 1. Distribution and Utilization**
- 2. Changes to product distribution process**
- 3. Weekly Reporting Requirements**
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- 5. Treatment guidelines and logistical constraints**
- 6. State/Territorial best practices for allocation**
- 7. Prevalence of Delta Variant Nationally**
- 8. Sotrovimab Product Overview**
- 9. Frequently Asked Questions**
- 10. Upcoming webinars and helpful resources**
- 11. Discussion / Q&A**

Distribution and utilization summary

2.9M

Shipped through all Tx programs¹

8,489

Number of sites shipped to¹

1.54M

Total reported usage²

53%

% of distributed supply used³

1. Total for entire period 2. Total usage as reported since 12/9 3. Reported through date 10/8

Note: Number of sites, % of total stock on hand and total reported usage is updated weekly

Source: ABC Distribution reports, TeleTracking, State Reports

Current Distribution Process: State/Territory-Coordinated System

- HHS continues to take steps to better manage COVID-19 mAb supply to meet both current and anticipated COVID-19 caseloads
- The increase in the Delta variant of SARS-CoV-2, coupled with low vaccination rates in certain areas of the country has caused a substantial surge in the utilization of monoclonal antibody drugs over the July-August 2021 timeframe
- In September, HHS transitioned to a state/territory-coordinated distribution system similar to the system used in the Nov 2020-Feb 2021 timeframe

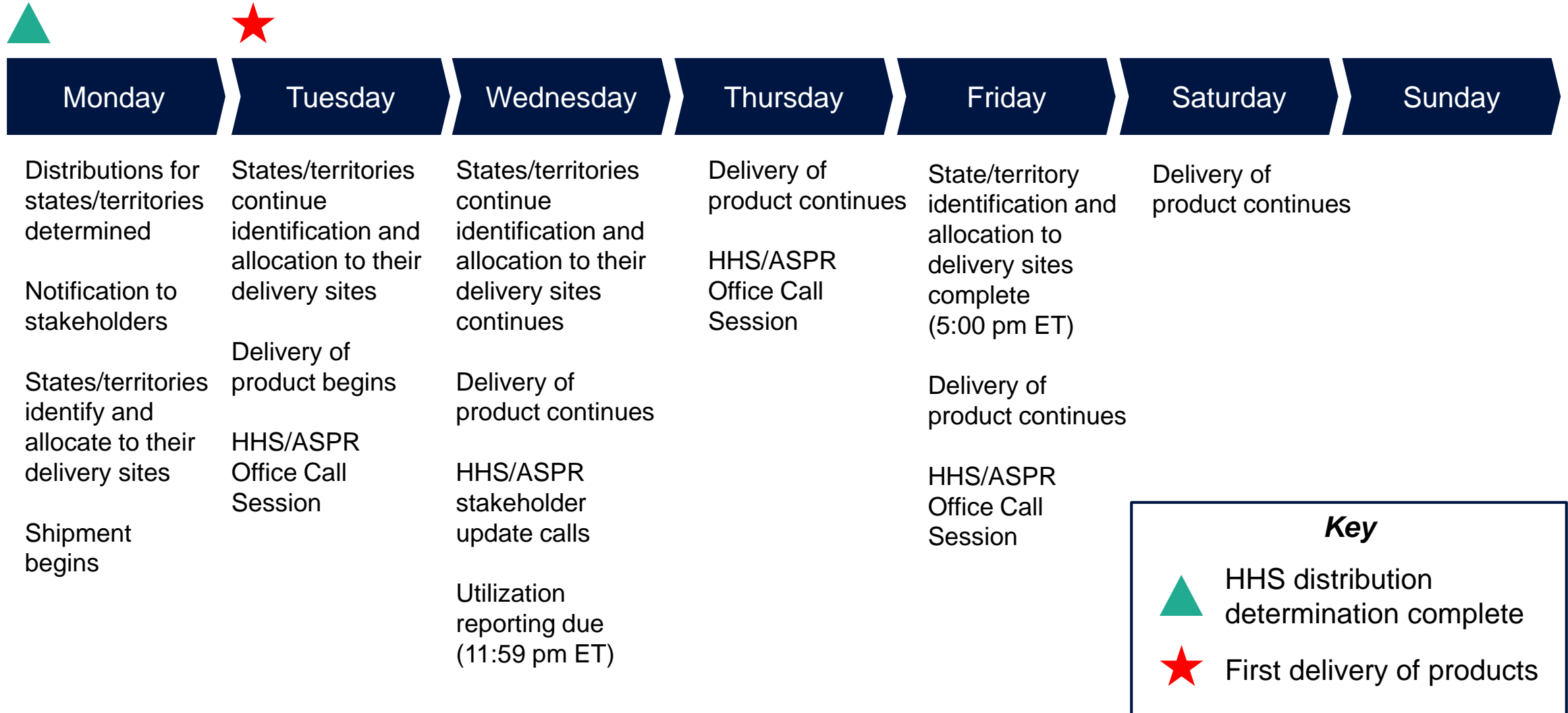
Pause in direct ordering; shift to state-territory coordinated distribution system

Current Distribution Process: State/Territory-Coordinated System

- State/territory-coordinated distribution system helps maintain equitable distribution, both geographically and temporally- providing states and territories with consistent, fairly-distributed supply over the coming weeks and while the USG works to procure additional supply
- Administration sites no longer order directly from the distributor
- USG determines weekly distribution amounts to states and territories
- State/Territorial Health Departments determine where product goes in their jurisdictions

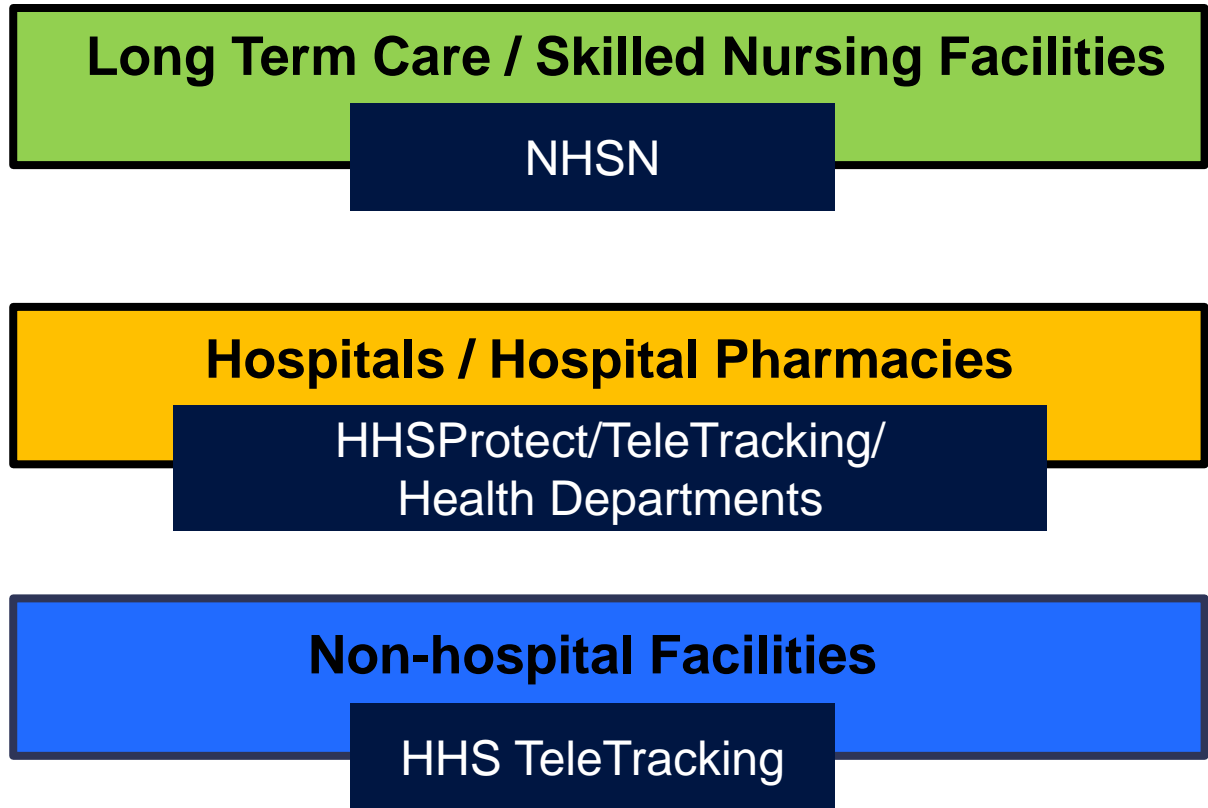
**USG determines weekly distribution amounts;
states/territories identify receiving sites and allocate amounts**

Distribution Determination and Shipment Rhythm



Reporting Requirements

Sites administering USG-purchased COVID-19 monoclonal antibody therapeutics must provide information regarding product utilization and stock on hand through CDC's National Healthcare Safety Network (**NHSN**), **HHS Protect**, **TeleTracking**, or through **state/territory health departments**, depending on facility type and jurisdictional guidance.



Weekly utilization reporting required by 11:59 pm each Wednesday

For additional information on reporting requirements, visit the site below:

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

Stewardship of Product

bamlanivimab/etesevimab

- Sites able to administer via intravenous infusion should utilize mAbs distributed to them
- Sites unable to utilize bamlanivimab/etesevimab due to inability to administer intravenously, contact your state/territorial health department for redistribution of product

REGEN-COV

- May be received in several different formulations, including co-formulation, or dose packs containing individual vials of casirivimab and imdevimab (not co-formulated) in 2.5 or 11.1 mL vials
- The 11.1 mL vials contain product for **two patient courses** (utilizing an 11.1 mL vial of casirivimab and an 11.1 mL vial or imdevimab)
- The vials may be used as multi-dose vials under COVID-19 allowances provided by the USP
- A mixed intravenous infusion may be refrigerated for up to 36 hours per EUA
- Vials, intravenous mixtures, and subcutaneous doses drawn up in syringes may be kept at room temperature for up to 4 hours

- **No product returns at this time.**
- **Coordinate with state/territorial health department for redistribution.**
- **Hold any expired product until receipt of further guidance from USG.**

- **Health departments encouraged to consider capabilities and storage capacity of receiving sites when determining allocations.**

COVID-19 treatment guidelines when there are logistical constraints

- The [COVID-19 Treatment Guidelines Panel](#) recommends using anti-SARS-CoV-2 monoclonal antibodies for the treatment of mild to moderate COVID-19 and for post-exposure prophylaxis (PEP) of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19, as outlined in the FDA Emergency Use Authorizations (EUAs). See [the individual EUAs](#) for details.
- Logistical constraints (e.g., limited space, not enough staff who can administer therapy) can make it difficult to administer these agents to all eligible patients. In situations where it is necessary to triage eligible patients, the Panel suggests:
 - **Prioritizing the treatment of COVID-19 over PEP of SARS-CoV-2 infection.**
 - **Prioritizing the following groups over vaccinated individuals who are expected to have mounted an adequate immune response:**
 - Unvaccinated or incompletely vaccinated individuals who are at high risk of progressing to severe COVID-19
 - Vaccinated individuals who are not expected to mount an adequate immune response (e.g., immunocompromised individuals).
- **Providers should use their clinical judgment** when prioritizing treatment or PEP in a specific situation. When there are no logistical constraints for administering therapy, these considerations **should not** limit the provision of anti-SARS-CoV-2 monoclonal antibodies.

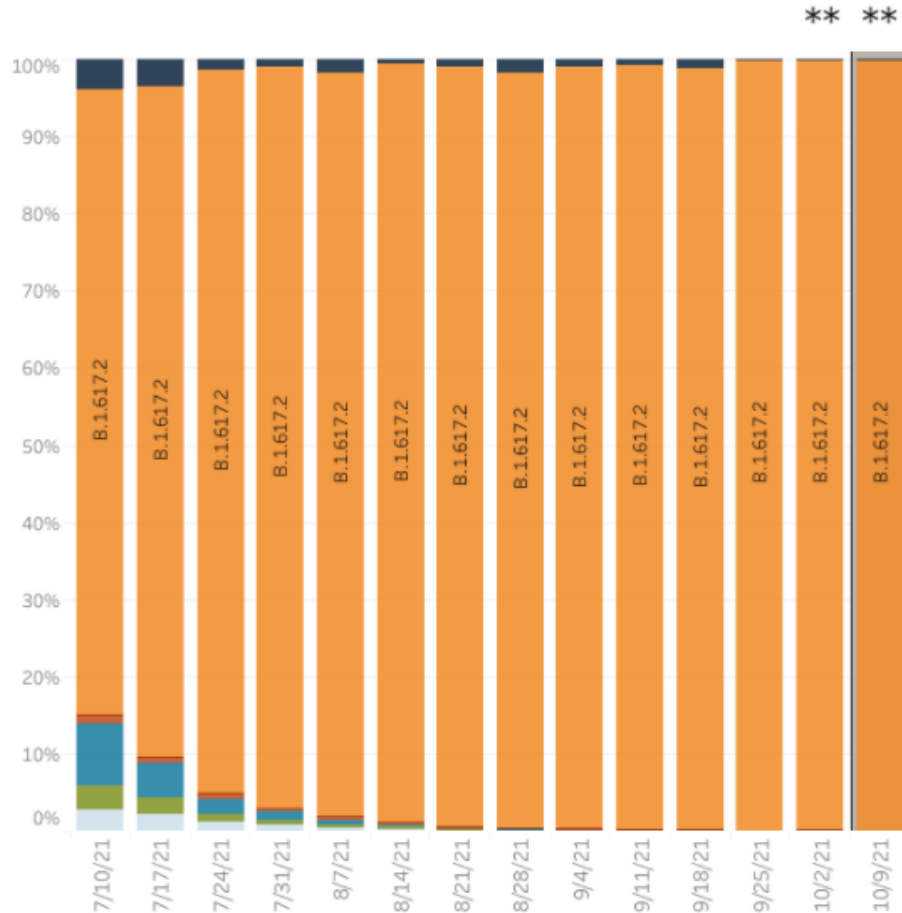
State and Territorial Health Department Best Practices for Facilitation of mAb Allocations

- Established organizational structure
 - Local facilities report up to county/parish level representatives
 - County/Parish representatives report to department of health (DOH)
 - DOH submits requests to distributor
 - Distributor ships product directly to administration sites
- Collection of requests via e-form
- Collection of requests via website or portal
- Collection of requests via dedicated email/inbox
- Use of data to determine how much to order for a particular county/parish
- DOH prioritizes requests based on data, utilization, equity, trends and usage
- DOH approves new sites based on data (i.e. increase of new cases)

Prevalence of Delta Variant Nationally

United States: 7/4/2021 – 10/9/2021

United States: 10/3/2021 – 10/9/2021 NOWCAST



USA				
WHO label	Lineage #	US Class	%Total	95%PI
Alpha	B.1.1.7	VBM	0.0%	0.0-0.0%
Gamma	P.1	VBM	0.0%	0.0-0.0%
Delta	B.1.617.2	VOC	99.9%	99.8-99.9%
	AY.1	VOC	0.0%	0.0-0.1%
	AY.2	VOC	0.0%	0.0-0.0%
Mu	B.1.621	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.1%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
 ** 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.1.621 are aggregated with the parent lineage and included in parent lineage's proportion. Q.1-Q.8 are aggregated with B.1.1.7. AY.3-AY.38 and their sublineages are aggregated with B.1.617.2.

- Delta (B.1.617.2) variant was at 31% nationally as of 6/19 and is **99.9% nationally as of 10/9** (pending data via [Nowcast](#))
- States/territories encouraged to reach out with questions/concerns
- **REGEN-COV, bam/ete, and sotrovimab are expected to retain activity to the Delta variant**

Sotrovimab Product Overview

Dr. Patrick Taylor
GlaxoSmithKline

Frequently Asked Questions (I/II)

Q1. Why did HHS transition from direct ordering to the state/territory-coordinated distribution system for COVID-19 mAbs?

The increased incidence of the Delta variant of SARS-CoV-2 caused a substantial surge in the utilization of monoclonal antibody (mAb) drugs, particularly in areas of the country with low vaccination rates. HHS is committed to helping ensure consistent availability of these critical drugs for current and future patients in all geographic areas of the country. As such, we updated the distribution process for mAbs to assure fairness and efficiency.

Q2. How do I reach my state/territorial health department point of contact?

If you do not know how to reach your health department POC, email HHS at COVID19Therapeutics@HHS.gov

Q3. How are COVID-19 monoclonal antibody therapeutics distributed under the state/territory-coordinated distribution system?

The current process is a state/territory-coordinated distribution system similar to that used to distribute mAb product from November 2020 – February 2021.

HHS firmly believes a state and territory-coordinated distribution system will help maintain equitable distribution, both geographically and temporally, across the country - providing states and territories with consistent, fairly-distributed supply over the coming weeks.

Under this system, HHS determines the weekly amount of mAb product available to each state and territory. Subsequently, state and territorial health departments then determine which sites in their jurisdictions receive product and how much.

Contact COVID19Therapeutics@hhs.gov with any questions

Frequently Asked Questions (II/II)

Q4. What formula or equation was used to determine distribution amounts for Cycle 5?

HHS looked at the past 7-day incident hospitalizations and case counts for each state/territory and the case counts for the entire country.

A state or territory's percentage of the country's 7-day incident hospitalizations and weighted 7-day incident case counts equals that state's percentage of the available amount of mAbs for distribution this week

This week's (Oct 11-17) baseline amount available for distribution was 175,000 doses. Approximately 8,000 additional doses were added to ensure no jurisdiction's distribution amount was cut more than 20% of what they received last week.

Q5. Can states/territories receive additional product above their determined distribution amount?

At this time, states and territories are not able to receive additional product above their weekly calculated amounts. It should be noted that the weekly distribution amounts are determined based on case burden and utilization within jurisdictions.

Q6. Does HHS set aside distribution amounts for federal entities?

Yes; this week, HHS determined separate distribution amounts for IHS, VHA, DOD, ICE.

IHS = Indian Health Service
DOD = Department of Defense

VHA = Veterans Health Administration
ICE = Immigration and Customs Enforcement

Q7. My distribution of mAbs was lost or destroyed in transit. Can it be replaced?

Yes! If your distribution of mAb products was lost or destroyed in transit, please contact HHS at COVID19Therapeutics@HHS.gov for assistance.

Q8. If my supply of etesevimab has expired, what should I do?

Expired product must not be administered to patients. Supplies of etesevimab that have reached their expiration date, and are already in distribution in a state, territory, or U.S. jurisdiction in which the product is currently authorized, may remain in distribution and be held until further direction received from ASPR.

Q9. Did HHS buy more COVID-19 monoclonal antibody therapeutics products?

Yes; HHS purchased about 1.8 million additional doses the week of 9/13 (to be delivered over the next few months), and also purchased doses of the GlaxoSmithKline/VIR mAb, Sotrovimab. Sotrovimab is included in this week's distribution determinations.

Q10. Will HHS transition back to the regular direct ordering process? If so, when?

HHS will continue to monitor product utilization rates, COVID-19 case burden, and overall availability of monoclonal antibody therapeutics to determine when we will shift back to the normal direct ordering process.



Weekly Stakeholder Engagements

- **Office Call Sessions: HHS / ASPR Distribution and Administration of COVID-19 Therapeutics –open to all with equity in the process**
 - Tuesdays (2:00-3:00PM ET)
 - Thursdays (2:00-3:00PM ET)
- **Stakeholder Call: State, Local, Tribal, and Territorial Health Officials**
 - Wednesdays (2:00-3:00PM ET)
- **Stakeholder Call: National Health Care and Medical Orgs and Associations**
 - Wednesdays (3:15-4:15PM ET)
- **Federal COVID-19 Response: Monoclonal Antibodies 101 Webinar *(NEW)***
 - Fridays (12:00-1:00PM ET); *Oct 1, Oct 15, Oct 29*
 - Target audience: new administration sites, health officials

<https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaWltejYzZz09>

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

Helpful information and resources (I/II)

Product resources:

- **HHS Protect Therapeutics Dashboard**
<https://protect.hhs.gov/workspace/module/view/latest/ri.workshop.main.module.084a09b4-bcd0-4a6b-817a-90afb7a3cd1d>
- **Guidance for Returning Product**
 - For bam and bam/ete, see [The Lilly Return Goods Procedure](#); detailed guidance can be found at: <https://www.lillytrade.com/>
 - For REGEN-COV, call 844-734-6643
- **Monoclonal Antibody Therapeutics Homepage**
<https://www.phe.gov/mabs>
- **COVID-19 Monoclonal Antibody Therapeutics Communications Toolkit**
<https://www.phe.gov/mabs-toolkit>
- **REGEN-COV: Subcutaneous Injection Instructions for Healthcare Providers**
<https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/REGEN-COV-Subcutaneous-Injection-Instructions-for-Healthcare-Providers.aspx>

Helpful information and resources (II/II)

Informational resources:

- **HHS/ASPR Website (mAbs):** phe.gov/mAbs
- **HHS Website:** <https://combatcovid.hhs.gov/>
- **ASPR Regional Teams**
 - Consult [the ASPR Regional Team in your area](#) for questions regarding COVID-19 medical countermeasures
- **ASPR TRACIE** [general hurricane resources](#)
- **HRSA Uninsured Program** [fact sheet](#)
- **Updated information sheets and resources for providers in English and Spanish** <https://combatcovid.hhs.gov/hcp/resources>
- **Increased CMS reimbursement rates for mAb administration:** <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>



Thank you!