



Update: Distribution and Administration of COVID-19 Therapeutics

NOVEMBER 17, 2021

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

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Agenda

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Distribution and utilization summary

3.52M

Shipped through all Tx programs¹

9,197

Number of sites shipped to¹

1.91M

Total reported usage²

54.2%

% of distributed supply used³

1. Total for entire period 2. Total usage as reported since 12/9 3. Reported through date 11/17

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

- 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**

About The Current Distribution: Cycle 10 (Nov 15-28)

- No change to base distribution methodology
- Current distribution is for a two-week cycle
 - Offer flexibility and prevent disruption over holiday week
 - No new distribution determinations on Nov 22
 - Product can be ordered throughout entire cycle up to allocated amount
- Distributing about 176,332 total doses of mAbs this cycle
 - REGEN-COV (88,692), bam/ete (52,474), sotrovimab (35,166)
 - Distributing to state/territorial health departments, federal partners
 - **Note: REGEN-COV Roche Packs are 11.1mL (not 10mL) and 2.5 mL (not 25 mL)**
- Product not identified by health departments for allocation to jurisdictions by 5:00 pm ET on Friday, Nov 26th will be “swept” for re-allocation
- USG contacting S/THOs in jurisdictions with high ordering + low utilization/high stock on hand to better understand needs; allocations for those jurisdictions may be adjusted

Current Distribution Cycle Spans Two Weeks

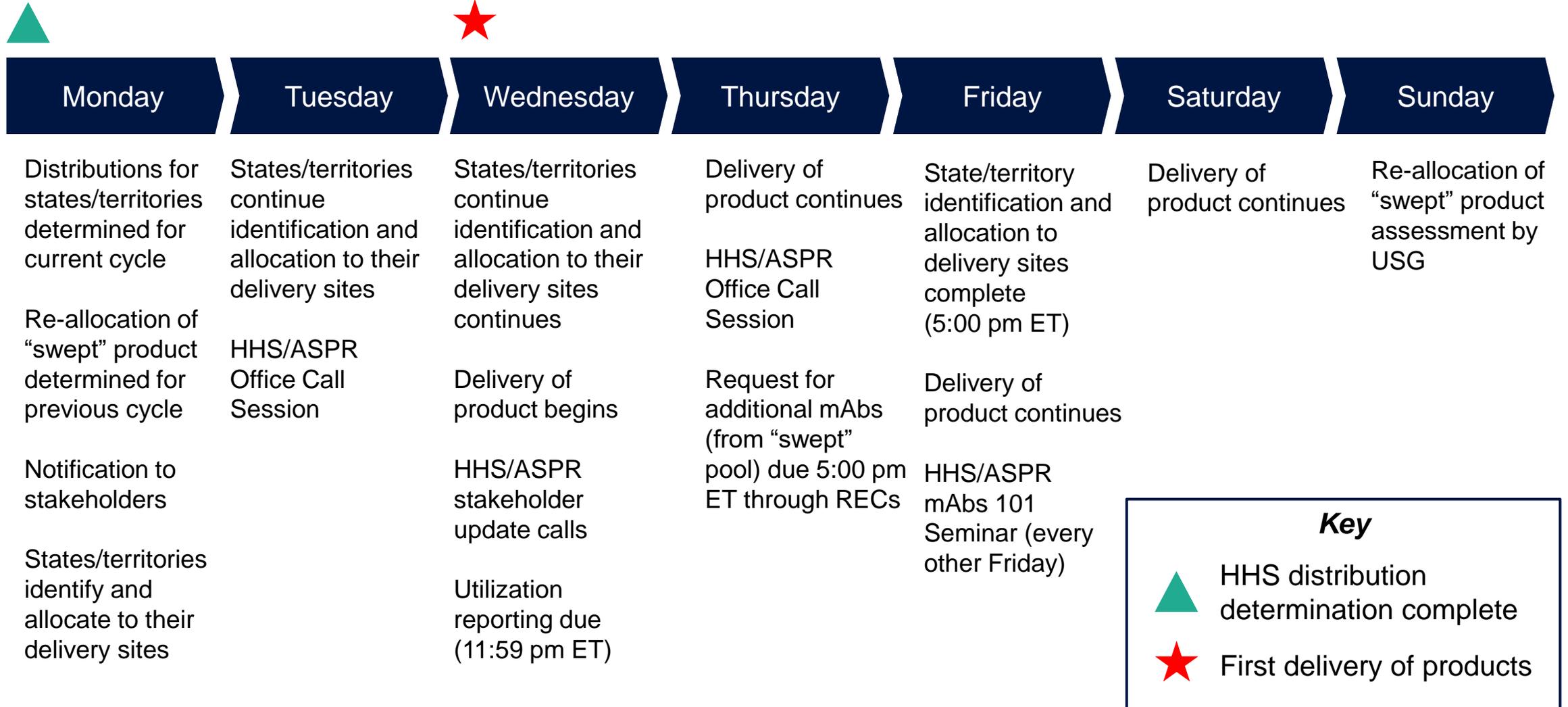
Weekly Re-allocation of “Swept” Product

- National decrease in COVID-19 cases and hospitalizations
- Some areas of country still experiencing increase in cases; need for additional mAbs above weekly allocation
- USG implemented same-cycle re-allocation of mAbs not identified for distribution by health departments
- mAbs not identified for distribution by 5:00 pm ET on Fridays are “swept” for re-allocation to needed jurisdictions; cut-off is 5:00 pm ET on Friday, Nov 26th for Cycle 10
- Health department officials can request a portion of “swept” mAbs through respective ASPR/REC if the jurisdiction:
 - Has reported in HHSProtect mAb utilization equivalent to at least 70% of their allocation from the previous distribution cycle
 - Has reported in HHSProtect an inventory on hand of less than 3 weeks of mAb product based on utilization and current inventory as reported for the previous distribution cycle

Same-cycle re-allocation of mAbs not identified for distribution by health departments

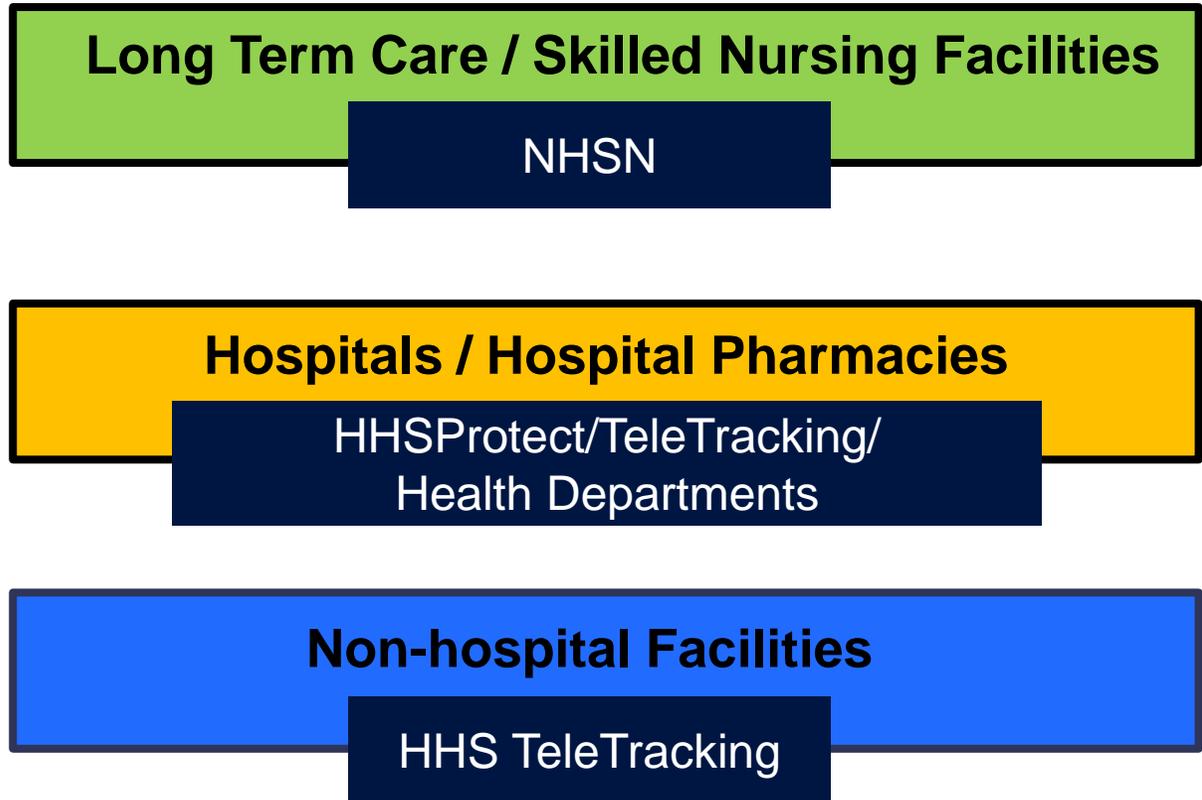
Distribution Determination and Shipment Rhythm

Cycle 10: Nov 15-28 (two-week cycle)



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.**

- 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.

Overview: Health Partner Ordering Portal (HPOP)

What is HPOP Therapeutics?

- A therapeutics ordering portal which will eventually replace the Amerisource Bergen C-19 portal for therapeutics

HPOP Therapeutics Onboarding

- Mandatory for all jurisdictional partners
- Required forms (submitted to the region's government sponsor)
 - New Partner Request Form (1 per partner)
 - New User Access Request Form (1 per contact)
 - HHS Rules of Behavior (1 per contact)
- All forms are required to be **completed by Nov 19, 2021 (Friday)**

HPOP Terminology

Partners
(Central
Partners)

- Jurisdictions: ie Florida, Puerto Rico
- Pharmacy: ie Walgreens Corporate Office
- Federal Entity: BoP, IHS, DoD

Providers

- Individual pharmacies: ie Walgreens store #1234
- Hospitals, clinics, doctor's office, dialysis center

Contacts
(Users)

- Individuals who can login to HPOP

HPOP use is mandatory for all jurisdictional partners
Onboarding deadline: Friday, Nov 19, 2021

Overview: Health Partner Ordering Portal (HPOP)

HPOP Therapeutics Demonstrations/Training Sessions

- Jurisdictional partners need only attend one session
 - Nov 19 @3:00 – 4:30 pm ET
 - Nov 22 @3:00 – 4:30 pm ET
 - Dial in info (same for all dates/times)
 - <https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSDhUZ2I0Y0NhZkUxVlkxdz09>
 - Passcode: 257470
 - Webinar ID: 160 304 7233

HPOP Therapeutics Timeline

- Nov 19: HPOP partners and contacts complete onboarding forms
- Nov 24: HPOP partner contacts begin to receive registration emails
 - Partners can then begin loading provider site data and provider contacts
 - Provider contacts will need to log in, verify address/hours, and sign attestation
- Nov 30: Earliest day that therapeutics threshold could be set for partners to apportion

Please contact your ASPR Regional Emergency Coordinator should you have questions.

Planning for Future COVID-19 Therapeutics

➤ What we know:

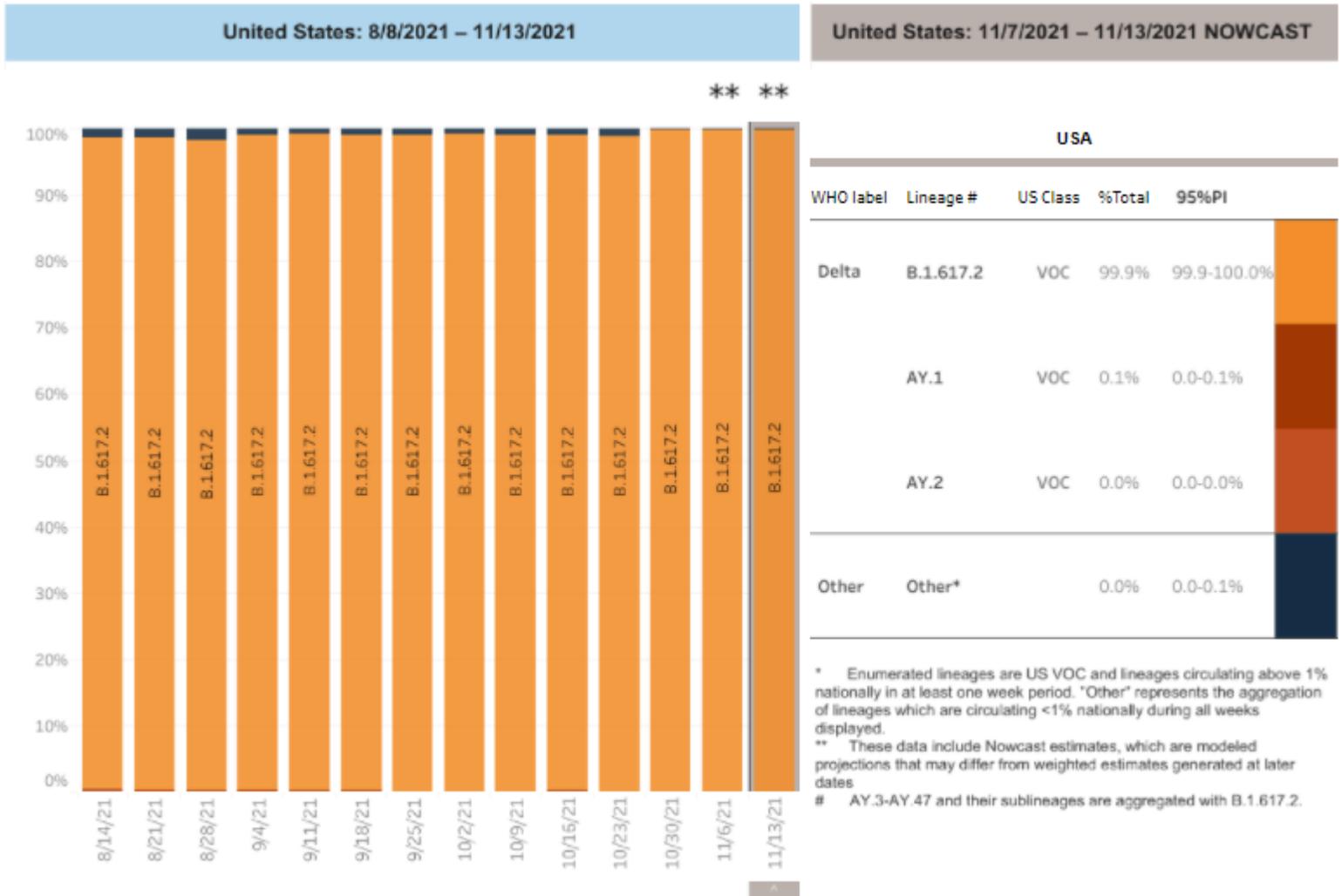
- AstraZeneca submitted application in October to FDA for Emergency Use Authorization (EUA) for AZD7442, a long-acting antibody (LAAB) combination, for prophylaxis of symptomatic COVID-19
- Merck submitted application in October to FDA for EUA for molnupiravir, an investigational oral antiviral medicine, for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization

➤ What we're doing:

- Preliminary engagements with state and territorial health officials to receive feedback as USG develops distribution plans (contingent upon products' receipt of EUA)
- Preliminary engagements with pharmacy organizations/associations to receive feedback as USG develops distribution plans (contingent upon products' receipt of EUA)
- Awaiting FDA decision

The FDA has received EUA applications for additional COVID-19 therapeutics.

Prevalence of Delta Variant Nationally



- Delta (B.1.617.2) variant was at 31% nationally as of 6/19 and is **99.9% nationally as of 11/17** (pending data via [Nowcast](#))
- States/territories encouraged to reach out with questions/concerns
- **REGEN-COV, bam/ete, and sotrovimab are all expected to retain activity to the Delta variant**

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 through 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 9?

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 distribution (Nov. 15-28) included approximately 176,000 doses of mAbs.

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

If jurisdictions have met certain requirements, they may request a portion of weekly mAbs not allocated by other state/territorial health officials. Health department officials must make such requests through the appropriate ASPR REC. A list of the ASPR RECs with contact information can be found [here](#).

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

Yes; this week, HHS determined separate distribution amounts for Department of Health and Human Services, Department of Veterans Affairs, Department of Defense, Department of Homeland Security, and Department of State.

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. 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.

Q9. Will the distribution of product be affected over the coming holidays in November and December?

The current distribution period will cover two weeks (Nov 15 – 28) in an effort to help provide flexibility for ordering around holiday schedules and to ensure administration sites do not experience delivery disruptions during the week of Thanksgiving. Product may be ordered during the entire two-week period, up to the allocated amount. It should be noted that there will be NO NEW DISTRIBUTIONS THE WEEK OF NOV 22.

Q10. What is HPOP and is it mandatory for state/territorial health departments to use this system?

HPOP is the Health Partner Ordering Portal - a therapeutics ordering portal which will eventually replace the Amerisource Bergen C-19 portal for therapeutics. All jurisdictional partners must use this system, once employed for the ordering of therapeutics. Training is available and health departments are encouraged to work through their ASPR RECs should they have questions.



Weekly Stakeholder Engagements

- **Office Call Sessions: HHS / ASPR Distribution and Administration of COVID-19 Therapeutics –open to all with equity in the process**
 - Tuesdays (2:00-2:30PM ET)
 - Thursdays (2:00-2:30PM ET) – **No session, Thursday, Nov 25th**
- **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: Therapeutics 210 Webinar**
 - Every other Friday (12:00-1:00PM ET); Next session – *Dec 3*
 - 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-mono-clonal-antibodies>



Thank you!