# Update: Distribution and Administration of COVID-19 Therapeutics

DECEMBER 1, 2021

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

# Agenda

1. Distribution and Utilization Overview
2. Current Product Distribution Process
3. This Week's Distributions
4. Re-allocation of "Swept" mAbs
5. Reporting Requirements
6. Treatment Guidelines and Logistical Constraints
7. HPOP Overview
8. Planning for Future Therapeutics
9. Prevalence of Delta Variant Nationally
10. Frequently Asked Questions
11. Upcoming webinars and helpful resources
12. Discussion / Q&A

# Distribution and utilization summary

| | |
|---|---|
| **3.6M** | Shipped through all Tx programs[1] |
| **9,290** | Number of sites shipped to[1] |
| **2.1M** | Total reported usage[2] |
| **58.3%** | % of distributed supply used[3] |

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 11 (Nov 29-Dec 12)

- No change to base distribution methodology
- Current distribution is for a two-week cycle
  - **Product can be ordered throughout entire cycle up to allocated amount**
- Distributing about 201,592 total doses of mAbs this cycle
  - REGEN-COV (111,492), bam/ete (90,100 ), sotrovimab (0)
  - REGEN-COV (Regeneron) and bam/ete (Lilly) are included in the distribution for cycle 11
  - No sotrovimab (GSK) is included for distribution during this cycle
  - We have substantially more bam/ete (Lilly) in stock and as a result did not include sotrovimab (GSK) in this cycle's distribution
  - Moving forward, we expect a 50:50 ratio of REGEN-COV to bam/ete and/or sotrovimab
  - Approved requests for additional product will likely be filled with bam/ete; receiving jurisdictions should plan accordingly
  - Distributing to state/territorial health departments, federal partners

**Current Distribution Cycle Spans Two Weeks**

# About The Current Distribution: Cycle 11 (Nov 29-Dec 12)

- Product not identified by health departments for allocation to jurisdictions by **5:00 pm ET on Friday, Dec 10th** 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 (Federal Pool)

- Some areas experiencing increase in cases; need for additional mAbs above standard allocation
- USG implemented same-cycle re-allocation of mAbs not identified for distribution by health depts.
- mAbs not identified for distribution by 5:00 pm ET on the second Friday of the two-week distribution cycle are "swept" into the Federal Pool for re-allocation to needed jurisdictions; cut-off for Cycle 11 is 5:00 pm ET on Friday, Dec 10th
- Health department officials can request a portion of "swept" mAbs from the Federal Pool through their ASPR/REC if the jurisdiction:
  - Has reported in HHSProtect mAb utilization of 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**

# Weekly Re-allocation of “Swept” Product (Federal Pool)

- The Federal Pool is in place to support jurisdictions that may have an immediate need for more mAbs above their allocated amount. The Federal Pool allows equitable access to product that other jurisdictions did not need and did not order.
- To date, in most weeks, the majority of REGEN-COV is ordered by jurisdictions leaving less REGEN-COV product for the Federal Pool.
- Alternative products (such as bam/ete) are more readily available in the Federal Pool to support jurisdictions’ requests. As such, jurisdictions that are experiencing higher demand for patient treatments should consider adjusting programs to also be able to use bam/ete to meet patient needs, if appropriate.

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

# Distribution Determination and Shipment Rhythm

## Cycle 11: Nov 29 – Dec 12

| Monday | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |
|---|---|---|---|---|---|---|
| Distributions for states/territories determined for current cycle<br><br>Re-allocation of "swept" product determined for previous cycle<br><br>Notification to stakeholders<br><br>States/territories identify and allocate to their delivery sites | States/territories continue identification and allocation to their delivery sites<br><br>HHS/ASPR Office Call Session | States/territories continue identification and allocation to their delivery sites continues<br><br>Delivery of product begins<br><br>HHS/ASPR stakeholder update calls<br><br>Utilization reporting due (11:59 pm ET) | Delivery of product continues<br><br>HHS/ASPR Office Call Session<br><br>Request for additional mAbs (from "swept" pool) due 5:00 pm ET through RECs | State/territory identification and allocation to delivery sites complete (5:00 pm ET on Dec 10th)<br><br>Delivery of product continues<br><br>HHS/ASPR Therapeutics 210 Seminar; every other Friday | Delivery of product continues | Re-allocation of "swept" product (Federal Pool) assessment by USG |

***Key***

▲ HHS distribution determination complete

★ First delivery of products

# Reporting Requirements

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

**Long Term Care / Skilled Nursing Facilities**

NHSN

**Hospitals / Hospital Pharmacies**

HHSProtect/TeleTracking/
Health Departments

**Non-hospital Facilities**

HHS TeleTracking

**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

# COVID-19 treatment guidelines when there are logistical constraints

- The NIH 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.

# Storage Requirements for COVID-19 mAbs*

| | bamlanivimab/etesevimab | casirivimab/imdevimab (REGEN-COV) | sotrovimab |
|---|---|---|---|
| **Storage of UNOPENED VIALS in original carton** | **Refrigerated** (2-8°C/36-46°F): until expired | **Refrigerated** (2-8°C/36-46°F): until expired<br>**Room temperature** (up to 25°C/ 77°F): 30 days | **Refrigerated** (2-8°C/36-46°F): until expired |
| **Storage of PREPARED IV SOLUTION** | **Refrigerated** (2-8°C/36-46°F): 24 hours<br>**Room temperature** (20-25°C/ 68-77°F): 7 hours | **Refrigerated** (2-8°C/36-46°F): 36 hours<br>**Room temperature** (up to 25°C/ 77°F): 4 hours | **Refrigerated** (2-8°C/36-46°F): 24 hours<br>**Room temperature** (up to 25°C/ 77°F): 6 hours |
| **Storage of PREPARED SYRINGES**** | n/a | **Refrigerated** (2-8°C/36-46°F): 24 hours<br>**Room temperature** (up to 25°C/ 77°F): 8 hours | n/a |
| **Time to Equilibrate to Room Temperature before Administration (Per EUA language)** | Approximately 20 minutes | 30 minutes | Approximately 15 minutes |

For most up to date information, refer to product EUA Fact Sheets:
http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf
https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS
*NOTE: Temperature ranges and specifications are per each product EUA*
* The United States Pharmacopeia has created allowances for COVID-19 therapeutics outlined at https://go.usp.org/l/323321/2020-04-11/345w2b.
The monoclonal antibodies do not require a hood for preparation. Storage times noted in the product EUAs are regardless of whether a hood was used for preparation.
** REGEN-COV EUA updated November 2021 to reflect increased storage time for syringes prepared for subcutaneous administration

# Reminder: 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 were due **Nov 19, 2021.**

**HPOP Terminology**

| | |
|---|---|
| Partners (Central Partners) | • Jurisdictions: i.e., Florida, Puerto Rico<br>• Pharmacy: i.e., Walgreens Corporate Office<br>• Federal Entity: BoP, IHS, DoD |
| Providers | • Individual pharmacies: i.e., Walgreens store #1234<br>• Hospitals, clinics, doctor's office, dialysis center |
| Contacts (Users) | • Individuals who can login to HPOP |

**HPOP use is mandatory for all jurisdictional partners.**

# Reminder: Health Partner Ordering Portal (HPOP)

- **HPOP Activation Emails**
  - Expire after 72 hours
  - Emails will come from “VTrckS Provider Ordering Portal,” **vpop-no-reply@cdc.gov**
  - Organizations should whitelist this address in email servers, firewalls, etc.

- **Federal Retail Pharmacy Therapeutics Partners (FRPTP)**
  - FRPTP providers are exclusively managed by the FRPTP itself
  - Jurisdictional partners must not add FRPTP providers
  - Jurisdictions must work with the FRPTP partner to setup those relationships

**Please contact your ASPR Regional Emergency Coordinator if you have questions.**

# Reminder: Health Partner Ordering Portal (HPOP)

**HPOP Therapeutics Timeline**

- **Nov 19:** HPOP partners and contacts complete HPOP & Tiberius onboarding forms

- **Nov 30:** Jurisdictions access Tiberius Site Selection Planning Tool;
  - Begin creating files for AZ and Merck Therapeutic provider sites (2 files only)
  - Tiberius requires separate onboarding from HPOP
  - Each jurisdiction has an Optumserve contractor supporting Tiberius

- **Nov 30:** Jurisdictions email site selection files to CAG for processing (HPOP-Therapeutics@hhs.gov)

- **Nov 25-30 :** HHS processes jurisdiction site selection files

- **Dec 1:** HPOP partner contacts begin to receive registration emails
  - Contacts must log in (email expires after 72 hours)
  - Partner reviews current providers (active status, categorization, and state pin)
  - Partners add missing provider addresses & categorize them as “monoclonal special” or “antiviral”

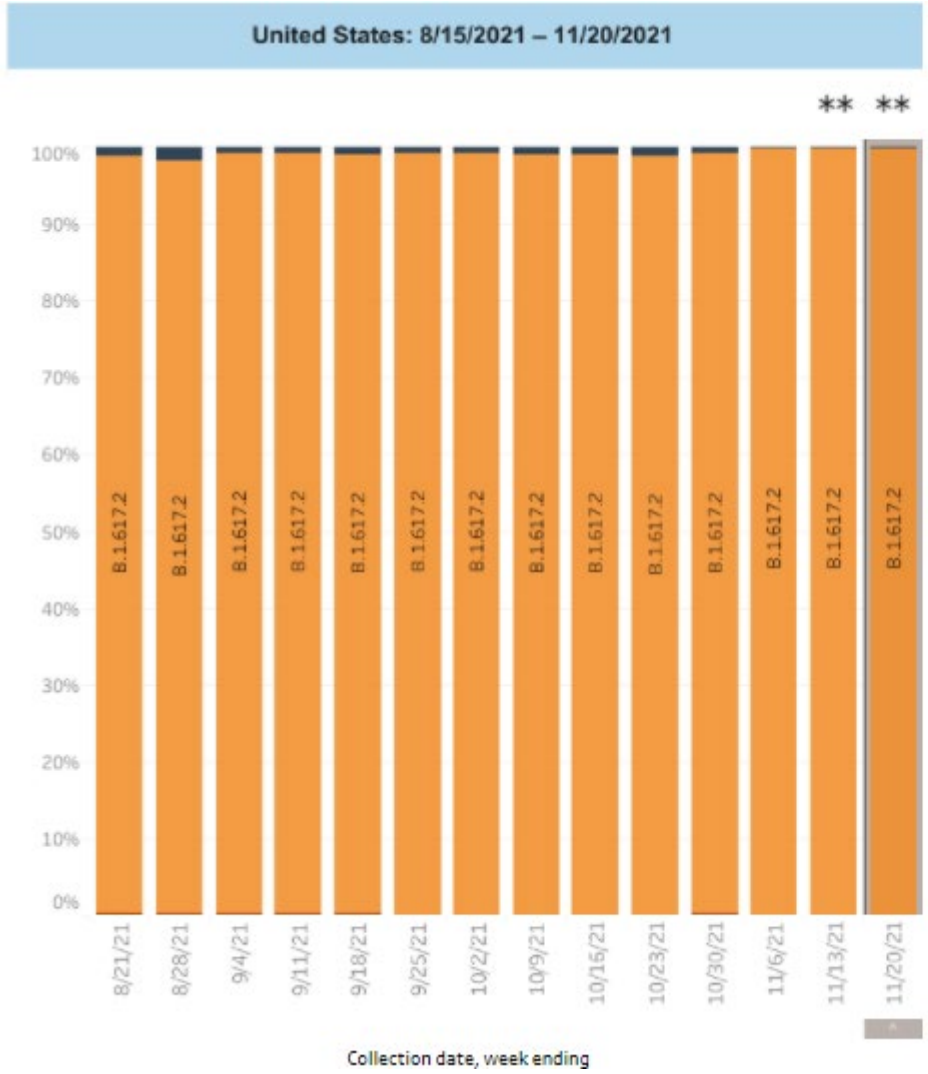
- **Dec 2-UTC (tentative):** HPOP provider contacts begin to receive registration emails
  - Partners upload or enter provider contacts to send out these emails
  - Provider contacts must log in (email expires after 72 hours) and sign attestation
  - Providers verify address/hours, enter license #/expiry

# Planning for Future COVID-19 Therapeutics

- **What we know:**
  - AstraZeneca submitted an application to FDA for Emergency Use Authorization (EUA) for AZD7442, a long-acting antibody (LAAB) combination, for prophylaxis of symptomatic COVID-19
  - Merck and Pfizer submitted applications to FDA for EUA for molnupiravir and Paxlovid, respectively, investigational oral antiviral drugs, 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:**
  - Engagements with state and territorial health officials for planning as USG develops distribution plans (contingent upon products' receipt of EUA)
  - Engagements with pharmacy organizations/associations 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




United States: 11/14/2021 – 11/20/2021 NOWCAST

USA

| WHO label | Lineage # | US Class | %Total | 95%PI |
|---|---|---|---|---|
| Delta | B.1.617.2 | VOC | 99.9% | 99.8-100.0% |
| | AY.1 | VOC | 0.1% | 0.0-0.2% |
| | AY.2 | VOC | 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
# AY.3-AY.120 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 11/29** (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 11?

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 29–Dec 3) included approximately 201,592 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 ofmAb 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 holidays?

HHS will maintain a two-week distribution cycle through the end of December in an effort to help provide flexibility for ordering around holiday schedules and to ensure administration sites do not experience delivery disruptions. Product may be ordered during the entire two-week period, up to the allocated amount. The current distribution cycle spans Nov 29 – Dec 12.

## 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. 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)
- **Stakeholder Call: State 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
- **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)

- **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!