Update: Distribution and Administration of COVID-19 Therapeutics

OCTOBER 6, 2021

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

Agenda

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13. Discussion / Q&A

Distribution and utilization summary

2.83M	Shipped through all Tx programs[1]
8,455	Number of sites shipped to[1]
1.44M	Total reported usage[2]
51%	% of distributed supply used[3]

1. Total for entire period 2. Total usage as reported since 12/9 3. Reported through date 9/29
Note: Number of sites, % of total stock on hand and total reported usage is updated weekly
Source: ABC Distribution reports, TeleTracking, State Reports

Change to 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
- Beginning Monday, September 13, 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

Change to Distribution Process: State/Territory-Coordinated System

- State/territory-coordinated distribution system will help 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

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Distributions for states/territories determined Notification to stakeholders States/territories identify and allocate to their delivery sites Shipment begins	States/territories continue identification and allocation to their delivery sites Delivery of product begins HHS/ASPR Office Call Session	States/territories continue identification and allocation to their delivery sites continues Delivery of product continues HHS/ASPR stakeholder update calls Utilization reporting due (11:59 pm ET)	Delivery of product continues HHS/ASPR Office Call Session	State/territory identification and allocation to delivery sites complete (5:00 pm ET) Delivery of product continues HHS/ASPR Office Call Session	Delivery of product continues	

Key

HHS distribution determination complete

First delivery of products

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.

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

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 are 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 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)

USG Purchase of Sotrovimab

Preparation

Sotrovimab is supplied in a single-dose vial and must be diluted prior to administration.
Sotromivab injection should be prepared by a qualified healthcare professional using aseptic technique.

- Gather the materials for preparation
  - Polyvinyl chloride (PVC) or polyolefin (PO), sterile prefilled infusion bag. Choose one of the following sizes: prefilled 50-mL or 100 – mL infusion bag containing 0.9% Sodium Chloride Injection, and
  - One vial of sotrovimab (500 mg/8 mL).

- Remove one vial of sotrovimab from refrigerated storage and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes.
- Inspect the vial of sotrovimab visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded, and a fresh solution prepared.
  - Sotrovimab is a clear, colorless or yellow to brown solution

- Gently swirl the vial several times before use without creating air bubbles. **Do not shake the vial.**

- Withdraw 8 mL sotrovimab from one vial and insect into a prefilled infusion bag containing 0.9% Sodium Chloride Injection.

- Discard any product remaining in the vial.

- Prior to the infusion, gently rock the infusion bag back and forth by hand 3 to 5 times. **Do not invert the infusion bag.** Avoid forming air bubbles.

- This product is preservative-free; therefore, the diluted infusion solution should be administered immediately.
  - If immediately administration is not possible, store the diluted solution of sotrovimab up to 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) or refrigerated up to 24 hours (2°C to 8°C [36°F to 46°F])

Administration

- Infuse over 30 minutes
- Do NOT deliver via IV push or IV bolus
- Monitor patient for 60 minutes after infusion

[Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab]
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS

CDC variants of concern by state

Estimated biweekly proportions of the most common SARS-CoV-2 lineages circulating in the U.S available from the [CDC variant proportions data tracker]

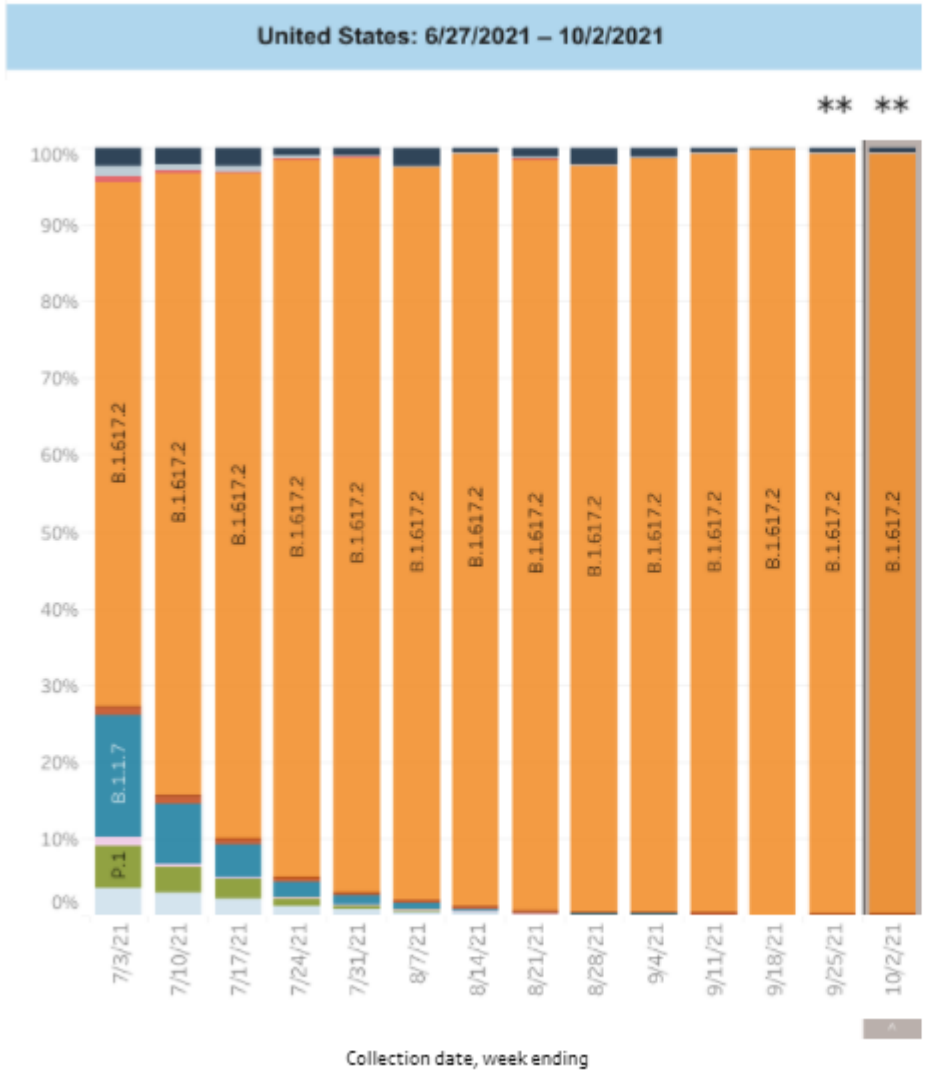
Unweighted Proportions of Variants of Concern and Other Lineages by State or Jurisdiction

State	B.1.1.7	B.1.351	P.1	B.1.617.2	AY.1	AY.2	B.1.526	B.1.617.1	B.1.621	Other	Total Available sequences
Alabama	0.11%		0.06%	94.55%		0.17%				5.10%	1,763
Alaska	0.29%			97.99%					1.15%	0.57%	348
Arizona				96.49%	0.12%	0.06%				3.34%	1,707
Arkansas			0.15%	97.84%		0.15%				1.85%	649
California	0.07%		0.14%	97.72%	0.52%	0.49%		0.00%	0.08%	0.97%	23,287
Colorado	0.05%			98.25%		0.05%			0.05%	1.60%	2,059
Connecticut	0.09%			98.31%	0.09%	0.09%			0.38%	1.04%	1,062
Delaware				99.43%						0.57%	523
District of Columbia	0.17%			99.17%	0.33%					0.33%	604
Florida	0.16%	0.01%	0.13%	95.01%	0.01%	0.04%			0.09%	4.55%	9,273
Georgia	0.05%		0.03%	97.45%		0.02%			0.16%	2.29%	6,152
Idaho				99.31%	0.10%					0.59%	1,017
Illinois			0.10%	95.92%	0.13%	0.07%			0.27%	3.51%	2,967
Indiana	0.18%			95.63%		0.18%				4.00%	1,624
Iowa				96.74%						3.26%	582
Kansas				98.12%						1.88%	744
Kentucky	0.04%		0.04%	98.31%		0.31%				1.29%	2,252
Louisiana	0.23%			94.80%						4.97%	885
Maryland	0.06%			98.73%		0.06%			0.12%	1.03%	1,650
Massachusetts	0.01%		0.07%	99.18%	0.01%	0.06%			0.18%	0.49%	10,811
Michigan				97.22%	0.10%					2.68%	970
Minnesota				99.02%	0.04%				0.06%	0.88%	5,086
Mississippi			0.12%	97.65%						2.24%	850
Missouri			0.06%	96.61%					0.06%	3.27%	1,680
Nebraska				98.01%						1.99%	553
Nevada				98.81%	0.06%	0.50%				0.63%	1,590
New Hampshire				99.15%						0.85%	585
New Jersey			0.03%	98.98%	0.07%	0.03%			0.20%	0.68%	2,947
New Mexico	0.10%			98.38%					0.10%	1.43%	1,047
New York			0.06%	98.61%	0.24%	0.15%			0.33%	0.62%	3,376
North Carolina	0.11%		0.04%	97.57%		0.02%			0.18%	2.09%	5,683
Ohio			0.06%	97.98%	0.12%	0.06%			0.09%	1.69%	3,263
Oklahoma				95.31%						4.69%	512
Oregon	0.16%		0.08%	98.73%	0.16%	0.16%				0.71%	1,260
Pennsylvania	0.21%		0.05%	98.61%		0.05%				1.08%	1,945
Rhode Island			0.71%	98.67%	0.09%					0.53%	1,130
South Carolina	0.04%		0.04%	97.34%	0.04%	0.04%			0.04%	2.45%	2,328
Tennessee	0.02%		0.05%	96.20%	0.02%	0.07%			0.03%	3.61%	5,953
Texas	0.05%	0.01%	0.15%	95.52%		0.02%			0.05%	4.20%	9,836
Utah				96.24%	0.33%	0.82%				2.61%	612
Vermont				100.00%							1,671
Virginia	0.04%		0.13%	99.11%	0.18%				0.09%	0.44%	2,254
Washington	0.08%		0.08%	99.45%	0.08%	0.02%	0.02%		0.23%	0.06%	5,248
West Virginia				98.57%					0.16%	1.26%	1,824
Wisconsin				98.37%	0.05%				0.27%	1.31%	1,836
Wyoming				98.02%					0.33%	1.65%	303

Variant proportions are based on representative CDC sequence data (NS3 + CDC-funded contract sequencing) collected over a 4-week period ending Sep. 11, 2021 for states with at least 300 sequences.

Updated Sep. 28, 2021

Prevalence of Delta Variant Nationally



United States: 9/26/2021 – 10/2/2021 NOWCAST

USA

WHO label	Lineage #	US Class	%Total	95%PI
Alpha	B.1.1.7	VBM	0.0%	0.0-0.2%
Beta	B.1.351	VBM	0.0%	0.0-0.2%
Gamma	P.1	VBM	0.0%	0.0-0.2%
Delta	B.1.617.2	VOC	99.4%	98.6-100.0%
	AY.1	VOC	0.1%	0.0-0.5%
	AY.2	VOC	0.0%	0.0-0.2%
Iota	B.1.526	VBM	0.0%	0.0-0.2%
Kappa	B.1.617.1	VBM	0.0%	0.0-0.2%
Mu	B.1.621	VBM	0.0%	0.0-0.2%
N/A	B.1.628		0.0%	0.0-0.2%
	B.1.637		0.0%	0.0-0.2%
Other	Other*		0.5%	0.0-1.2%

* Enumerated lineage are VOC/VOI as well as those 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, B.1.351 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.32 and their sublineages are aggregated with B.1.617.2.

United States: 9/26/2021 – 10/2/2021 NOWCAST

- Delta (B.1.617.2) variant was at 31% nationally as of 6/19 and is **99.4% nationally as of 10/2** (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**

REGEN-COV™ (casarivimab and imdevimab) Product Overview

Configurations and Support Information

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 will COVID-19 monoclonal antibody therapeutics be distributed under the updated system?

The updated 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 this week's distribution amounts

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 baseline amount available for distribution was 175,000 doses. Approximately 15,000 additional doses were added to ensure no jurisdiction's distribution amount was cut more than 20% of what they received last week.

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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. 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.

Q7. Does HHS set aside distribution amounts for federal entities?

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

Q8. Will HHS buy more COVID-19 monoclonal antibody therapeutics products?

Yes; HHS is considering all available options for procuring additional product.

HHS purchased about 1.8 million additional doses the week of 9/13 (to be delivered over the next few months), and also recently purchased doses of the GlaxoSmithKline/VIR mAb, Sotrovimab.

Q9. 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.

IHS = Indian Health Service
DOD = Department of Defense
NIH = National Institutes of Health
VHA = Veterans Health Administration
ICE = Immigration and Customs Enforcement

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!