Update: Distribution and Administration of COVID-19 Therapeutics

SEPTEMBER 22, 2021

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

Agenda

1. Distribution and Utilization
2. Changes to product distribution process
3. Weekly Reporting Requirements
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10. Discussion / Q&A

Distribution and utilization summary

2.52M	Shipped through all Tx programs[1]
8,098	Number of sites shipped to[1]
1.2M	Total reported usage[2]
48%	% of distributed supply used[3]

1. Total for entire period 2. Total usage as reported since 12/9 3. Reported through date 9/20
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

Tuesday

Distributions for states/territories determined

Notification to stakeholders

States/territories identify and allocate to their delivery sites

Shipment begins

HHS/ASPR Office Call Session

Wednesday

States/territories continue identification and allocation to their delivery sites

Delivery of product begins

HHS/ASPR stakeholder update calls

Utilization reporting due (11:59 pm ET)

Thursday

States/territories continue identification and allocation to their delivery sites continues

Delivery of product continues

HHS/ASPR Office Call Session

Friday

State/territory identification and allocation to delivery sites complete (5pm ET)

Delivery of product continues

Key

HHS distribution determination complete

First delivery of products

Reporting Requirements

Sites administering USG-purchased COVID-19 monoclonal antibody thereapeutics 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

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- 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

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.

Expanded EUA for bamlanivimab / etesevimab: Post-Exposure Prophylaxis

bamlanivimab / etesevimab now authorized for post-exposure prophylaxis in individuals who are:

- Adult or pediatric (≥ 12 years of age and weighing at least 40kg) patient **at high risk for progressing to severe COVID-19 disease or death (*see high risk criteria)***
- 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 bamlanivimab and etesevimab is not a substitute for vaccination against COVID-19

bamlanivimab and etesevimab together are 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

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 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. An additional 25,000 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. Does HHS set aside distribution amounts for federal entities?

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

Q7. 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 last week (to be delivered over the next few months).

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.

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

CDC variants of concern by state

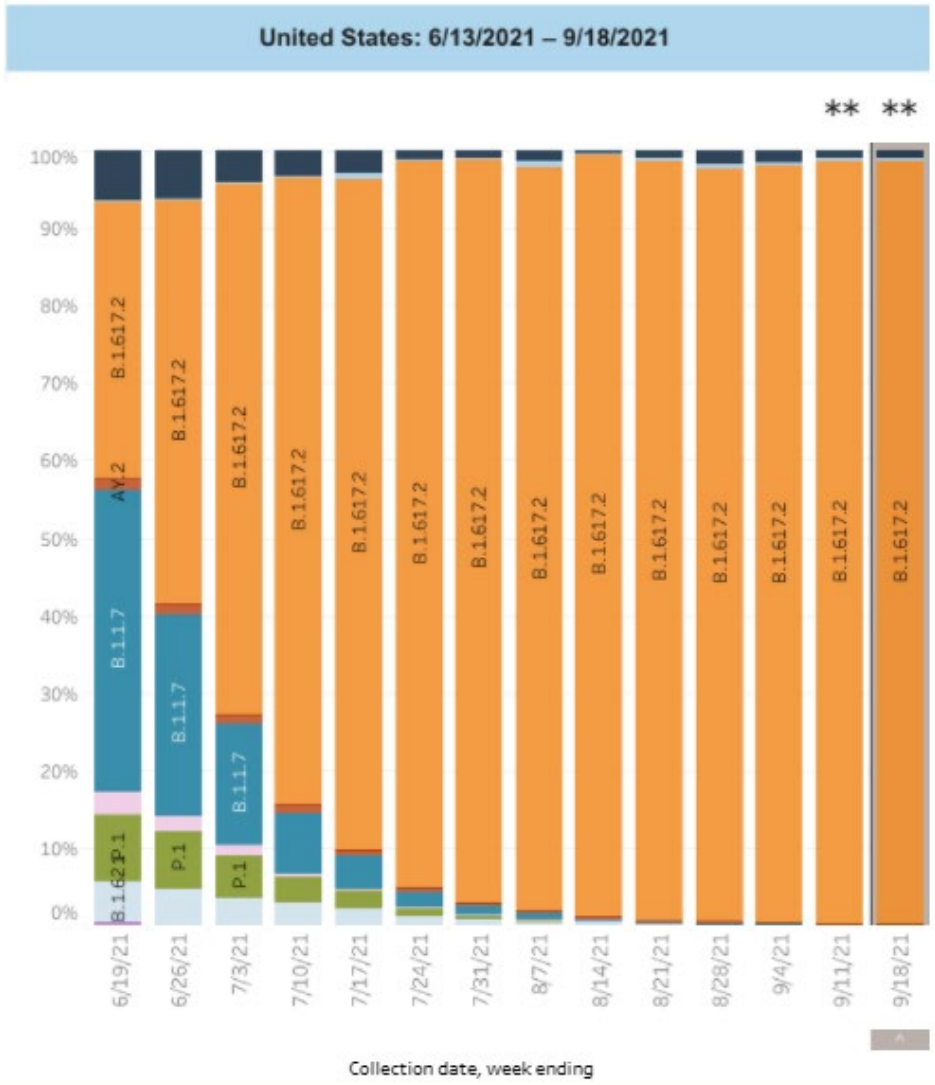
Estimated biweekly proportions of the most common SARS-CoV-2 lineages circulating in the U.S available from the [CDC variant proportions data tracker]

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	0.65%		0.29%	94.69%	0.12%	0.04%			0.04%	4.16%	2,449
Arizona	0.25%		0.51%	95.66%	0.10%	0.30%			0.15%	2.93%	1,980
Arkansas			0.14%	96.97%		0.43%			0.29%	2.16%	693
California	0.21%		0.27%	96.75%	0.60%	0.64%	0.00%	0.00%	0.27%	1.23%	32,509
Colorado	0.26%	0.13%	0.10%	97.87%	0.13%	0.20%			0.29%	0.95%	3,051
Connecticut	0.24%		0.12%	97.94%		0.12%			0.36%	1.21%	827
Delaware				98.55%	0.21%				0.62%	0.62%	484
District of Columbia				99.21%	0.20%					0.59%	507
Florida	0.55%		0.44%	93.21%	0.01%	0.08%	0.02%		0.59%	5.10%	13,307
Georgia	0.18%		0.18%	96.86%	0.01%	0.10%			0.29%	2.37%	7,259
Idaho	0.15%			98.46%					0.31%	1.08%	649
Illinois	0.18%		0.09%	95.34%	0.09%	0.22%			0.26%	3.78%	2,273
Indiana	0.46%		0.09%	95.78%						3.67%	1,091
Iowa	0.29%			94.43%	0.29%					4.99%	341
Kansas				97.57%		0.15%			0.15%	2.13%	658
Kentucky	0.36%		0.12%	97.17%	0.06%	0.36%			0.12%	1.81%	1,662
Louisiana	1.81%		0.07%	92.26%						5.86%	1,383
Maryland	0.28%		0.22%	97.48%	0.06%	0.11%			0.34%	1.45%	1,789
Massachusetts	0.04%		0.30%	98.11%	0.12%	0.09%			0.33%	0.97%	9,143
Michigan			0.17%	95.91%		0.34%			0.17%	3.41%	587
Minnesota			0.07%	98.66%		0.05%	0.02%		0.02%	1.17%	4,117
Mississippi	0.10%		0.21%	96.27%			0.10%			3.32%	965
Missouri	0.07%		0.15%	95.52%		0.07%			0.07%	4.11%	1,338
Nebraska				98.45%						1.55%	322
Nevada	0.14%		0.07%	97.26%	0.14%	0.62%				1.78%	1,462
New Hampshire				98.62%						1.38%	363
New Jersey	0.06%		0.06%	97.69%	0.09%	0.09%			0.72%	1.25%	3,199
New Mexico	0.34%			97.74%						1.92%	886
New York	0.14%		0.25%	97.71%	0.41%	0.08%			0.52%	0.80%	3,622
North Carolina	0.25%		0.16%	97.26%	0.01%	0.03%	0.06%		0.21%	1.99%	6,689
Ohio			0.12%	97.51%			0.06%		0.12%	2.19%	1,644
Oklahoma				92.18%						7.62%	499
Oregon	0.87%		0.58%	96.36%	0.22%	0.36%	0.07%		0.29%	1.24%	1,374
Pennsylvania	0.24%		0.12%	98.61%			0.12%		0.06%	0.84%	1,658
Rhode Island			0.82%	97.42%					0.10%	1.65%	970
South Carolina	0.31%			96.62%		0.09%			0.18%	2.81%	2,276
Tennessee	0.33%		0.08%	94.59%	0.05%	0.11%			0.19%	4.64%	3,661
Texas	0.41%	0.01%	0.35%	93.93%	0.05%	0.12%			0.32%	4.73%	10,368
Utah			0.15%	95.71%		0.59%			0.59%	2.96%	676
Vermont	0.17%		0.08%	99.58%					0.08%		1,191
Virginia	0.27%		0.18%	98.40%	0.14%	0.27%	0.05%		0.05%	0.64%	2,188
Washington	0.31%		0.20%	98.68%	0.09%	0.16%	0.02%		0.31%	0.22%	4,462
West Virginia	0.10%		0.41%	97.82%		0.21%			0.10%	1.35%	965
Wisconsin	0.07%		0.07%	97.54%					0.30%	2.01%	1,342

Variant proportions are based on representative CDC sequence data (NS3 + CDC-funded contract sequencing) collected over a 4-week period ending August 28, 2021 for states with at least 300 sequences.

Prevalence of Delta variant nationally



United States: 9/12/2021 – 9/18/2021 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	98.4%	97.1-99.5%
	AY.1	VOC	0.1%	0.0-0.5%
	AY.2	VOC	0.1%	0.0-0.5%
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	0.1%	0.0-0.2%
N/A	B.1.1.194		0.4%	0.0-1.0%
Other	Other*		1.0%	0.2-2.2%

* Enumerated lineages are VOI/VOC/VBM or are circulating >1% in at least one HHS region during at least one two week period. "Other" represents 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.25 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 **98.4% nationally as of 9/22** (pending data via Nowcast)
- States/territories encouraged to reach out with questions/concerns

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); *Beginning Oct 1*
  - 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!