



Update: Distribution and Administration of COVID-19 Therapeutics

SEPTEMBER 15, 2021

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

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Agenda

1. Update on distribution and utilization
2. Changes to product distribution process
3. Treatment guidelines in the event of logistical constraints
4. Reminder: Use and distro of bam/ete resumed nationally
5. Reminder: Extension of shelf-life for bam product
6. Update on COVID-19 variants of concern
7. Reminder: COVID-19 mAb therapeutics resources
8. Reminder: REGEN-COV post-exposure prophylaxis EUA
9. Reimbursement for subcutaneous admin of mAbs
10. Upcoming webinars and helpful resources
11. Discussion / Q&A

Distribution and utilization summary

2.39M Shipped through all Tx programs¹

8,003 Number of sites shipped to¹

1.08M Total reported usage²

44% % of distributed supply used³

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

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

Source: ABC Distribution reports, TeleTracking, State Reports

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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
- We firmly believe a state and 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**

Change to Distribution Process: State/Territory-Coordinated System

- Since November 2020, the United States Government (USG) has **worked to optimize availability** of the mAb therapeutics to healthcare facilities across the country.
- From **November 2020 – February 2021**, the **USG allocated Lilly and Regeneron monoclonal antibody products by state and territory**. State and territorial health departments directed distribution to administration sites within their jurisdictions.
- Once **enough product was available to meet full demand**, the USG shifted to a **direct ordering system**, allowing administration sites to order product directly from the USG's sole distributor (AmerisourceBergen)
- **USG continued to monitor supply and demand** across the country
- Surge in the Delta variant of SARS-CoV-2 coupled with low vaccination rates in certain areas of the country contributed to a rapid **20-fold increase in ordering from June to September 2021**, particularly in certain states that accounted for approximately 70% of mAb orders, and this is stressing overall product supply.

Change to Distribution Process: State/Territory-Coordinated System

- **Administration sites will NOT be able to order directly from the distributor**
- **The USG will determine weekly distribution amounts to states and territories**
- **Weekly distribution amounts will be determined based on weekly reports of new COVID-19 cases and hospitalizations in addition to data on inventories and use submitted in HHSProtect**
- **State/Territorial Health Departments will determine where product goes in their jurisdictions**
- **HHS Therapeutics team COVID19Therapeutics@hhs.gov will provide support to states during the transition**
- **Weekly distribution determinations posted on phe.gov/mabs**

Change to Distribution Process: State/Territory-Coordinated System

- Every Tuesday, HHS will send the **distribution numbers to the states/territories**
- **Specified state/territorial health official** determines **sites in their jurisdiction and amount of product each should receive** and logs into **ABC portal** to select sites and amount of product
- States/territories must designate sites/amount of product by **Friday of each distribution week**; product not designated will be “swept” back to the federal pool
- **Sites** log **stock on hand and utilization** into **HHSProtect weekly** in order to calculate distribution for each state/territory for the following week. (Utilization must be at least 70% of the previous week for the state/territory to receive their full calculated distribution the next week)

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 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)

Q3. What formula or equation will be used to determine the weekly distribution amounts?

HHS will first determine a state or territory's proportion of the country's total COVID-19 hospitalizations and confirmed cases, using a weighted average of these two numbers.

This percentage is equal to that state or territory's portion of the total amount of mAb products available for a given distribution week.

State/territory calculated amounts may be reduced if a state or territory's projected utilization is less than their calculated amount. Utilization of mAb product is reported each week through the HHSProtect TeleTracking data collection platform by administration sites, health departments, or other entities.

Q4. What formula or equation will be used to determine the weekly distribution amounts?

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.

Q5. Will HHS buy more COVID-19 monoclonal antibody therapeutics products?

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

Q6. 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.

Q7. Where can I find additional information about COVID-19 monoclonal antibody therapeutics?

Please visit phe.gov/mAbs to learn more about the state/territory-coordinated distribution system for mAbs.

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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.

Use and distro of **bamlanivimab and etesevimab (together)** resumed nationally due to Delta variant prevalence

Presence of variants

- The CDC has determined that the **frequency of the Delta variant (B.1.617.2**, first identified in India) is increasing throughout the U.S. and **has become the dominant variant in the country.**
- The results from in vitro studies suggest that:
 - Bamlanivimab and etesevimab (together) administered together **are active against the Delta variant (B.1.617.2)**



Impact on providers

- Effective 09/02/2021, **distribution of bamlanivimab and etesevimab administered together has resumed to all states, territories, and U.S. jurisdictions** given the combined frequency of variants resistant to bam / ete together is less than or equal to 5% nationwide.
- **For more information, please see**
 - [PHE.gov](https://www.phe.gov)
 - [FDA bam/ete Fact Sheet](#)

Please contact COVID19Therapeutics@hhs.gov with any questions

CDC variants of concern by state

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

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

State	B.1.1.7	B.1.351	P.1	B.1.617.2	AY.1	AY.2	Other	Total available sequences
Alabama	0.7%		0.3%	95.5%	0.2%	0.1%	3.2%	1,930
Arizona	0.3%		0.6%	96.2%	0.1%	0.4%	2.4%	1,567
Arkansas			0.2%	97.4%		0.5%	2.0%	615
California	0.2%		0.3%	97.0%	0.6%	0.7%	1.2%	30,527
Colorado	0.3%	0.2%	0.1%	97.9%	0.1%	0.2%	1.2%	2,569
Connecticut	0.3%		0.1%	98.5%		0.1%	1.0%	724
Delaware				98.9%	0.3%		0.8%	357
District of Columbia				99.7%			0.3%	356
Florida	0.6%		0.5%	93.8%	0.0%	0.1%	5.0%	10,977
Georgia	0.2%		0.2%	97.4%	0.0%	0.1%	2.0%	5,550
Idaho	0.2%			98.7%			1.1%	469
Illinois	0.3%		0.1%	96.6%	0.1%	0.2%	2.7%	1,536
Indiana	0.6%		0.2%	97.7%			1.5%	658
Kansas				98.4%		0.2%	1.4%	494
Kentucky	0.5%		0.1%	97.6%	0.1%	0.2%	1.5%	1,179
Louisiana	2.3%		0.1%	92.9%			4.8%	1,110
Maryland	0.3%		0.3%	97.8%	0.1%	0.1%	1.5%	1,389
Massachusetts	0.0%		0.3%	98.2%	0.1%	0.1%	1.2%	8,299
Michigan			0.3%	97.1%		0.5%	2.1%	375
Minnesota			0.1%	99.1%		0.1%	0.8%	3,799
Mississippi	0.1%		0.3%	96.9%			2.8%	762
Missouri	0.1%		0.1%	96.9%		0.1%	2.8%	973
Nevada	0.1%		0.1%	97.9%	0.1%	0.6%	1.3%	1,272
New Hampshire				99.1%			0.9%	319
New Jersey	0.1%		0.1%	97.7%	0.1%	0.1%	2.0%	2,728
New Mexico	0.4%			98.5%			1.1%	736
New York	0.2%		0.3%	97.8%	0.5%	0.1%	1.2%	3,117
North Carolina	0.3%		0.2%	97.9%	0.0%	0.0%	1.5%	5,379
Ohio			0.2%	98.4%			1.5%	1,160
Oklahoma				93.8%			6.2%	354
Oregon	1.0%		0.7%	96.1%	0.3%	0.4%	1.6%	1,129
Pennsylvania	0.3%		0.1%	99.1%			0.5%	1,319
Rhode Island			0.6%	97.7%			1.8%	724
South Carolina	0.4%			97.0%		0.1%	2.5%	1,621
Tennessee	0.5%		0.1%	95.3%	0.0%	0.1%	3.8%	2,209
Texas	0.5%		0.4%	95.4%	0.1%	0.1%	3.6%	8,316
Utah			0.2%	96.9%		0.8%	2.1%	519
Vermont	0.2%		0.1%	99.5%			0.2%	1,051
Virginia	0.3%		0.2%	98.4%	0.1%	0.3%	0.7%	1,817
Washington	0.3%		0.2%	98.6%	0.1%	0.2%	0.6%	4,194
West Virginia	0.1%		0.4%	98.4%		0.1%	0.9%	705
Wisconsin	0.1%		0.1%	98.4%			1.4%	996

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



- Delta (B.1.617.2) variant was at 31% nationally as of 6/19 and is **99.4% nationally as of 9/11** (pending data via [Nowcast](#))
- States/territories encouraged to reach out with questions/concerns

mAbs Weekly Stakeholder Engagements

- **Office Call Sessions: HHS / ASPR Distribution and Administration of COVID-19 Therapeutics – call all to 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 Sept 24*
 - 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

Upcoming webinars

Office Call Sessions HHS / ASPR Allocation, Distribution, Administration of COVID-19 Therapeutics

- **2x/week office call sessions**
- **Next call:** Thu, September 16, 2:00-3:00PM EST
- **Zoom link:** <https://bit.ly/3rfRv4E>
 - Meeting ID: 160 432 9034
 - Passcode: 897674

Weekly Stakeholder Update Calls

- **Next call:** Wed, September 22

Contact the Federal COVID-19 Response Team:
COVID19Therapeutics@hhs.gov

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!