



Update: Distribution and Administration of COVID-19 Therapeutics

JULY 28, 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 Four therapeutic pillars for equitable access
- 3 Reminder: National bam / ete and ete alone shipment pause
- 4 Update on variants of concern
- 5 Product ordering reminders
- 6 Upcoming webinars and helpful resources
- 7 Discussion / Q&A

Distribution and utilization summary

1.20M Shipped through all Tx programs¹

6,127 Number of sites shipped to¹

587K Total reported usage²

49% % of distributed supply used³

1. Total for entire period 2. Total usage as reported since 12/9 3. Reported through date 7/21

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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Four therapeutic pillars for equitable access



I. Home administration

Scale use of home administration to deliver mAbs and oral antivirals (to be incorporated in Pillar III)



II. Home delivery

Ensure 100% of population has access to antivirals by incorporating delivery into contracts and establishing partnerships



III. Rapid test to treat

Provide simplified patient referral pathway through partnerships with testing companies / telehealth providers



IV. Rapid response

Stand up rapid response capability (mobile units & SMEs – USG or contractor) to mobilize to identified community within 72 hours

Desired outcome

Reminder | National shipment pause of bam/ete and ete alone due to Beta (B.1.351) and Gamma (P.1) variant prevalence

Presence of variants

- In June, [CDC](#) identified **upward trends in the frequencies of the Beta variant (B.1.351**, first identified in South Africa) and the **Gamma variant (P.1**, first identified in Brazil) throughout the U.S.
- Results from in vitro studies suggest that:
 - Bam / ete administered together **are not active against** either Beta (B.1.351) or Gamma (P.1) variants
 - REGEN-COV and sotrovimab **are likely to retain activity** against Beta (B.1.351) and Gamma (P.1) variants

Impact on providers

- **Distribution of bam / ete together and etesevimab alone have been paused on a national basis until further notice**
- **FDA recommends health care providers use alternative authorized mAb therapies (REGEN-COV OR Sotrovimab) until further notice**
 - REGEN-COV can be ordered directly from Amerisource Bergen
 - Sotrovimab can be ordered via [GlaxoSmithKline's website](#)

Please contact COVID19Therapeutics@hhs.gov with any questions

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](#)

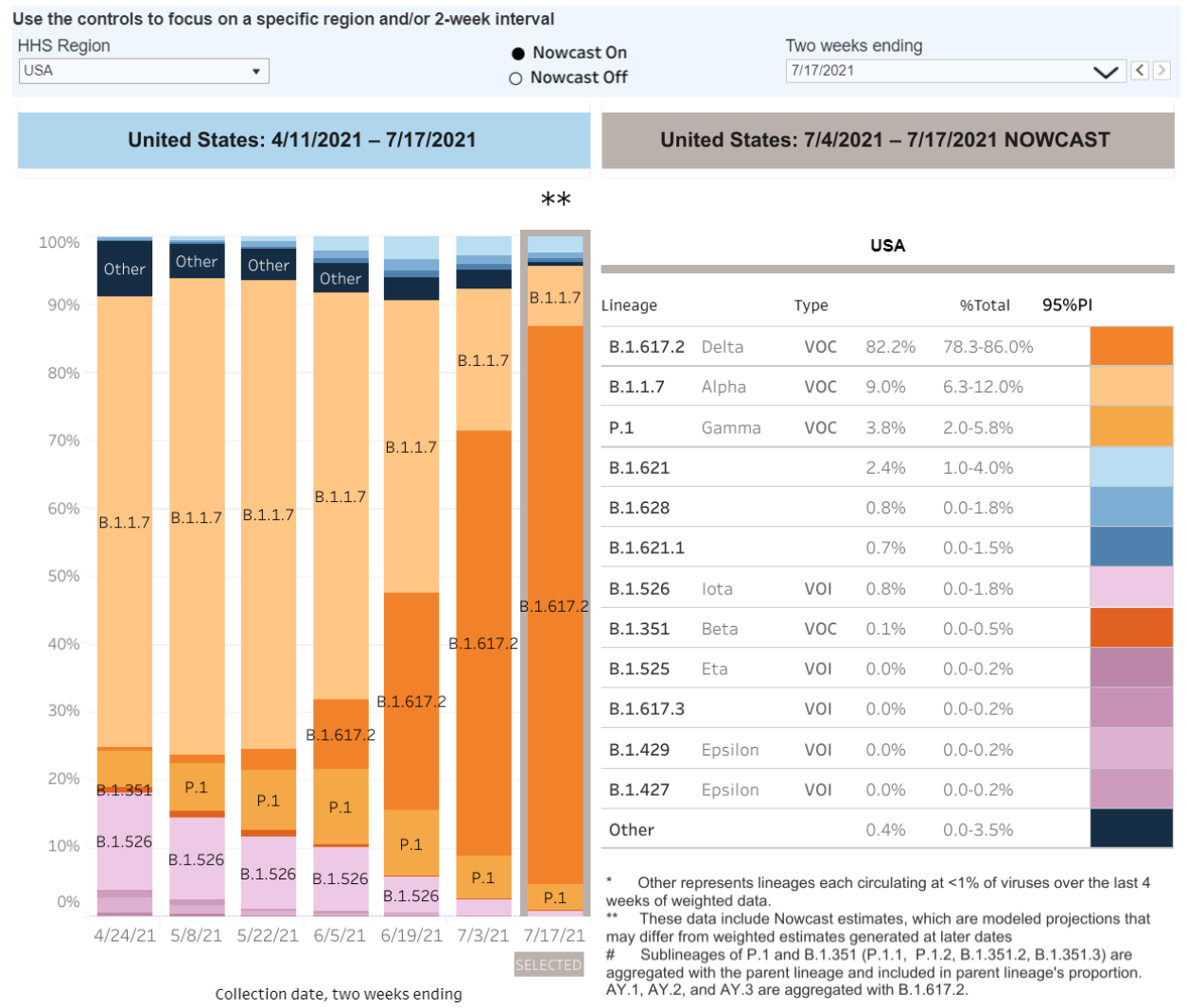
Unweighted Proportions of Variants of Concern and Other Lineages by State or Jurisdiction

| State | B.1.1.7 | B.1.351 | B.1.617.2 | P.1 | Other lineages | Total Available Sequences |
|----------------|---------|---------|-----------|-------|----------------|---------------------------|
| Arizona | 32.4% | | 37.2% | 18.7% | 11.7% | 487 |
| California | 22.8% | 0.1% | 56.8% | 9.0% | 11.3% | 4,332 |
| Colorado | 25.8% | | 66.9% | 3.8% | 3.5% | 1,282 |
| Florida | 33.8% | 0.0% | 36.8% | 13.4% | 16.0% | 2,688 |
| Georgia | 42.7% | | 39.9% | 6.7% | 10.7% | 522 |
| Illinois | 31.1% | | 49.0% | 11.9% | 8.0% | 498 |
| Massachusetts | 21.5% | | 27.1% | 12.6% | 38.8% | 446 |
| Missouri | 6.9% | | 90.3% | 1.1% | 1.7% | 1,000 |
| Nevada | 16.0% | 0.1% | 71.4% | 4.8% | 7.8% | 2,044 |
| New Jersey | 22.9% | | 56.6% | 6.4% | 14.1% | 846 |
| New York | 22.9% | | 41.0% | 9.0% | 27.1% | 402 |
| North Carolina | 35.6% | 0.2% | 38.8% | 5.0% | 20.4% | 963 |
| Oregon | 57.1% | | 11.5% | 16.7% | 14.7% | 312 |
| Texas | 31.9% | 0.0% | 45.9% | 6.2% | 16.0% | 2,737 |
| Washington | 35.9% | 0.2% | 40.7% | 13.3% | 9.8% | 1,261 |

Variant proportions are based on representative CDC sequence data (NS3 + CDC-funded contract sequencing) collected over a 4-week period ending July 3, 2021 for states with at least 300 sequences.

Updated July 27, 2021

Prevalence of Delta variant nationally



- B.1.617.2 (Delta) variant was at 31% nationally as of 6/19 and is **predicted to be at 82.2% nationally as of 7/17** (pending data via [Nowcast](#))
- States/territories encouraged to reach out with questions/concerns

CDC variants of concern susceptibility

- Information on variants of concern updated in **Section 15 of FDA fact sheets**

[REGEN-COV fact sheet](#)

[bamlanivimab / etesevimab fact sheet](#)

Table 6: Pseudotyped Virus-Like Particle Neutralization Data for SARS-CoV-2 Variant Substitutions with Casirivimab and Imdevimab Together

| Lineage with Spike Protein Substitution | Key Substitutions Tested | Fold Reduction in Susceptibility |
|---|----------------------------------|----------------------------------|
| B.1.1.7 (UK origin) | N501Y ^a | no change ^d |
| B.1.351 (South Africa origin) | K417N, E484K, N501Y ^b | no change ^d |
| P.1 (Brazil origin) | K417T + E484K ^c | no change ^d |
| B.1.427/B.1.429 (California origin) | L452R | no change ^d |
| B.1.526 (New York origin) ^e | E484K | no change ^d |
| B.1.617.1/B.1.617.3 (India origin) | L452R+E484Q | no change ^d |
| B.1.617.2 (India origin) | L452R+K478T | no change ^d |

Last revised 6/2021

Table 3: Pseudotyped Virus-Like Particle Neutralization Data for SARS-CoV-2 Variant Substitutions with Bamlanivimab and Etesevimab Together (1:2 Molar Ratio)

| Lineage with Spike Protein Substitution | Key Substitutions Tested ^a | Fold Reduction in Susceptibility |
|---|---------------------------------------|----------------------------------|
| B.1.1.7 (UK origin) | N501Y | no change ^b |
| B.1.351 (South Africa origin) | K417N + E484K + N501Y | 215 ^c |
| P.1 (Brazil origin) | K417T + E484K + N501Y | >46 ^c |
| B.1.427/B.1.429 (California origin) | L452R | 9 ^d |
| B.1.526 (New York origin) ^e | E484K | 31 |

^a For variants with more than one substitution of concern, only the substitution(s) with the greatest impact on activity is(are) listed. For B.1.351, P.1 and B.1.427/B.1.429, spike variants reflective of the consensus sequence for the lineage were tested.

^b No change: <5-fold reduction in susceptibility.

^c Bamlanivimab and etesevimab together are unlikely to be active against variants from this lineage. No activity observed at the highest concentration tested for the P.1 variant.

^d Etesevimab retains activity against this variant.

^e Isolates of the B.1.526 lineage harbor several spike protein amino acid substitutions, and not all isolates contain the E484K substitution (as of February 2021). This assay was conducted using pseudotyped VLPs with the E484K substitution only.

Last revised 5/2021

Product ordering reminders

- HHS/ASPR continues to manage the distribution of mAb products under EUA as stated in the FDA Letters of Authorization
- Please follow regional / state guidelines on products that can be requested via direct ordering for all sites



- Casirivimab/imdevimab supply is currently ample and **sites should not be hesitant to request additional supply**
- While there is a “federal review” for orders >48 patient courses, the review will not delay shipping
- **We recommend sites order sufficient supply to meet their next 2-week anticipated utilization**

Questions regarding ordering process:

- HHS: COVID19Therapeutics@hhs.gov
- Amerisource Bergen (ABC) commercial distributor: C19therapies@amerisourcebergen.com

Upcoming webinars

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

- **1x/week office call sessions**
- **Next call:** Thu, July 29, 2:00-2:30PM EST
- **Zoom link:** <https://bit.ly/3rfRv4E>
 - Meeting ID: 160 432 9034
 - Passcode: 897674

Weekly Stakeholder Update Calls

- **Next call:** Wed, August 4

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>
- **Direct Ordering Link via ABC**
<https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>
- **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

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!