Update: Allocation and Distribution of COVID-19 Therapeutics

APRIL 28, 2021

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

1. Update on utilization
2. Reminder: Revised NIH clinical guidelines for mAbs
3. Reminder: Revocation of bamlanivimab EUA / info. on variants
4. FEMA public assistance program
5. HRSA uninsured program
6. TeleTracking requirements
7. COVID-19 provider resources
8. Increasing mAb awareness – local communities
9. Upcoming webinars / helpful information
10. Discussion / Q&A
Distribution and utilization summary

- **987K**  Shipped through all Tx programs¹
  (allocations, direct orders, SPEED, pilots)

- **5,929**  Number of sites shipped to¹

- **453K**  Total reported usage²

- **46%**  % of distributed supply used³

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¹ Total for entire period
² Total usage as reported since 12/9
³ Reported through date 4/26

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

Source: ABC Distribution reports, TeleTracking, State Reports
The NIH has strongly recommended (AIIa) the following for use in non-hospitalized COVID-19 patients:

- Casirivimab + imdevimab (Regeneron)
- Bamlanivimab + etesevimab (Eli Lilly)

Updated NIH COVID-19 guidelines can be found at: https://www.covid19treatmentguidelines.nih.gov/statement-on-anti-sars-cov-2-monoclonal-antibodies-eua/
On April 16, 2021, the FDA revoked the emergency use authorization (EUA) that allowed for use of the investigational monoclonal antibody therapy bamlanivimab, when administered alone. Due to the sustained increase in variants resistant to bamlanivimab alone resulting in the increased risk for treatment failure and availability of alternative authorized mAbs.

USG stopped the distribution of bamlanivimab alone on March 24, 2021.

Sites that only have bamlanivimab and are administering monoclonal antibodies, should either:
- Order etesevimab to pair with the current supply of bamlanivimab
  OR
- Order and use the casirivimab + imdevimab monoclonal antibody cocktail

Information on direct ordering process available at:
https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/direct-order-process-covid19-mAb.aspx
Information available on SARS-CoV2 variants

- FDA Fact Sheets update antiviral resistance section 15 (bamlanivimab with etesevimab, and casirivimab with imdevimab) as information is available

- FDA Centers for Drug Evaluation and Research statement

- CDC updates on proportions of variants of concern by state (UPDATED!)

- CDC COVID-19 variant classifications and definitions (UPDATED!)

1. FDA factsheets: [https://www.fda.gov/media/145802/download](https://www.fda.gov/media/145802/download), [https://www.fda.gov/media/145611/download](https://www.fda.gov/media/145611/download), [https://www.fda.gov/media/145802/download](https://www.fda.gov/media/145802/download)

2. For variants with more than one substitutions of concern, only the one with the greatest impact of activity is listed

3. No activity was observed at the highest concentration tested.

4. Not all isolates of the New York lineage harbor the E484K substitution (as of February 2021)

   No change: <2-fold reduction in susceptibility for Cas+Imd, <5-fold reduction for Bam+Ete
FEMA Public Assistance Eligibility – COVID-19 Monoclonal Antibody Therapeutics

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Public Assistance (PA) provides supplemental disaster assistance to state, local, tribal, and territorial governments and certain private nonprofit (PNP) organizations.

PA eligibility is based on determining the eligibility of the Applicant, Facility, Work, and Costs in accordance with program authorities and policies.

- PNP eligibility is based both on determining Applicant eligibility and Facility eligibility based on the service provided.

Claimed work and associated costs must be the legal responsibility of the Applicant, required as a result of the declared event, and within an area authorized for PA.
FEMA Public Assistance: COVID-19 Medical Treatment

Eligibility is based on:
• Determining Applicant eligibility for Public Assistance;
• Validating that claimed costs are consistent with program authorities and policies; and
• Ensuring FEMA avoids any duplication of benefits (i.e., FEMA cannot provide assistance for any cost that is covered by another funding source).

FEMA is not going to question medical treatment decisions made by medical professionals at licensed medical care facilities.
COVID-19 medical treatment is covered under the FEMA Public Assistance COVID-19 Medical Care Policy

• Version 2 was released on March 15, 2021 to add provisions specific to COVID-19 vaccination efforts and address equity requirements

HRSA COVID-19 Uninsured Program: Brief Overview

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U.S. Department of Health and Human Services
Health Resources and Services Administration
COVID-19 Uninsured Program: Brief Overview

The HRSA COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured Program
More information available at: https://www.hrsa.gov/coviduninsuredclaim

Key Milestones

• April 22, 2020 – Program details launched
• April 27, 2020 – Providers began registering in the system at coviduninsuredclaim.linkhealth.com.
• April 29, 2020 – On demand training began
• May 6, 2020 – Claims submissions began electronically
• December 14, 2020 – Program began reimbursing for COVID-19 vaccine administration claims
Reporting via TeleTracking on COVID-19 therapeutics

Distribution to individual sites dependent on mandatory therapeutics reporting

Reporting via TeleTracking

- For each of the products, enter in quantities of product remaining on hand and of product used in the last week
- Quantity reported should be in patient courses
- Bamlanivimab solo usage and inventory should exclude bam part of bam / ete combos

If you need assistance setting up a Teletracking account or learn of sites having challenges reporting, email support at (COVID19Therapeutics@hhs.gov)
Updated factsheets and resources available for providers

Fact sheets are available at https://combatcovid.hhs.gov/hcp/resources
Please share with the providers in your network.
Increasing awareness of mAb treatments within local communities

- Leverage COVID-19 Monoclonal Antibody Therapeutics Digital Toolkit\(^1\) on Twitter, Facebook, Instagram or your other social media platforms
- Ensure local community awareness of mAb treatment centers
- Engage in outreach with community leaders
- Spread the word with large employers in your state as people come back to work
- Share information from manufacturers of COVID-19 therapies
  - Ex) Regeneron
    - 'Before anything': [https://www.youtube.com/watch?v=MYkjlFde3V1](https://www.youtube.com/watch?v=MYkjlFde3V1)
    - 'Monoclonal antibodies': [https://www.youtube.com/watch?v=27miAfxhl4E](https://www.youtube.com/watch?v=27miAfxhl4E)
- Leverage existing resources on phe.gov and CombatCOVID.hhs.gov to continue education

\(^1\) [https://www.phe.gov/emergency/events/COVID19/therapeutics/toolkit/Pages/default.aspx](https://www.phe.gov/emergency/events/COVID19/therapeutics/toolkit/Pages/default.aspx)
Office Call Sessions  HHS / ASPR Allocation, Distribution, Administration of COVID-19 Therapeutics
- **Next call:** Thu, Apr 29 2:00-2:30PM EST
- **Next call:** Tue, May 4 1:00-1:30PM EST
  - Meeting ID: 160 432 9034
  - Passcode: 897674

Weekly Stakeholder Update Calls
- **Next call:** Wed, May 5
Helpful information

- HHS/ASPR Website: [https://www.phe.gov](https://www.phe.gov)
- HHS Website: [https://combatcovid.hhs.gov/](https://combatcovid.hhs.gov/)
- ASPR Regional Teams
  - Consult the ASPR Regional Team in your area for questions regarding COVID-19 medical countermeasures
- HHSProtect Therapeutics Dashboard: [https://protect.hhs.gov/workspace/module/view/latest/ri.workshop.main.module.084a09b4-bcd0-4a6b-817a-90af7a3cd1d](https://protect.hhs.gov/workspace/module/view/latest/ri.workshop.main.module.084a09b4-bcd0-4a6b-817a-90af7a3cd1d)
- Direct Ordering Link via ABC: [https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8](https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8)
- Treatment Site locator tool [https://protect-public.hhs.gov/pages/therapeutics-distribution](https://protect-public.hhs.gov/pages/therapeutics-distribution)
- Reach out to the Federal COVID-19 Response Team: COVID19Therapeutics@hhs.gov
Thank you!