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 programs[1]
(allocations, direct orders, SPEED, pilots)

5,929 Number of sites shipped to[1]

453K Total reported usage[2]

46% % of distributed supply used[3]

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

Reminder | Revised NIH COVID-19 treatment guidelines

- 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/

Reminder | FDA revocation of bamlanivimab on April 16, 2021

- On April 16, 2021, **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**

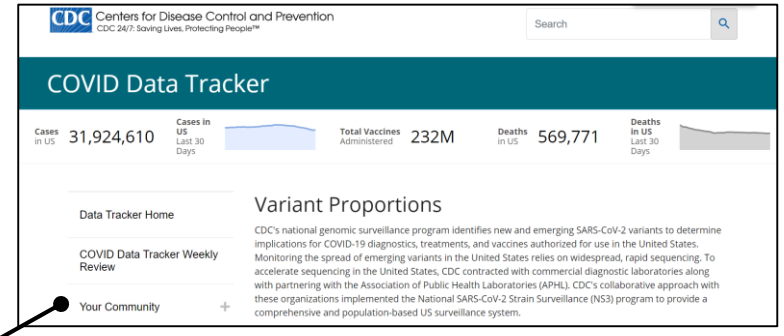
- USG **stopped the distribution of bamlanivimab alone** on March 24, 2021

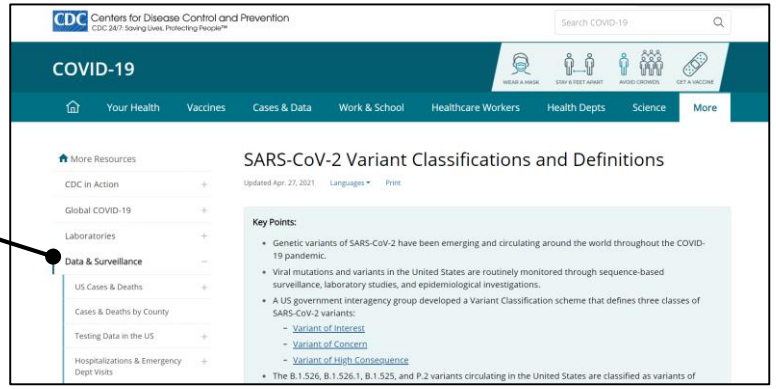
- Sites that only have bamlanivimab and are administering monoclonal antibodies, should either
  - Order etesevimab to pair with the current supply of bamlanivimab
    OR
  - order and use the casirivimab + imdevimab monoclonal antibody cocktail

- **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/145611/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

K.J. Retherford
Section Chief, Program Administration Section
Regulations and Policy Branch, Public Assistance Division
DHS/FEMA

FEMA Public Assistance: General Eligibility

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

FEMA Public Assistance: COVID-19 Medical Treatment

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

All Public Assistance COVID-19 guidance is available on FEMA.gov at: www.fema.gov/media-collection/public-assistance-disaster-specific-guidance-covid-19-declarations

5

HRSA COVID-19 Uninsured Program: Brief Overview

Maria LoPiccolo; Vonda Lawson

Legislative analyst; Program analyst

Health Resources and Services Administration (HRSA)

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

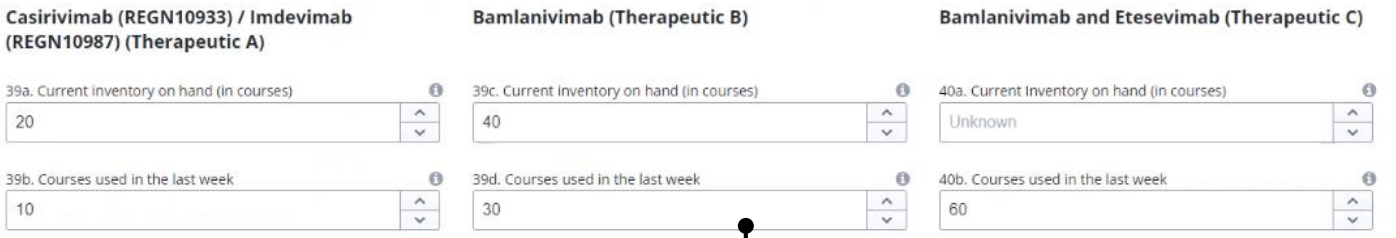
More information available at: https://www.hrsa.gov/coviduninsuredclaim

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**

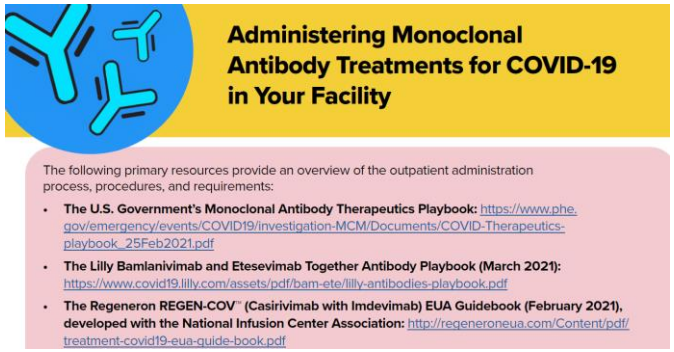


Reporting via TeleTracking

- 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)

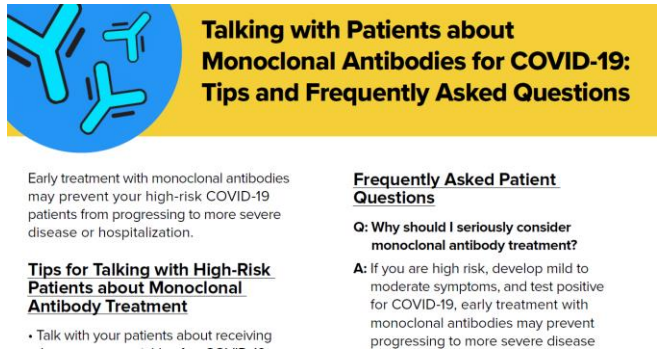
Updated factsheets and resources available for providers



Administering Monoclonal Antibody Treatments for COVID-19 in Your Facility

The following primary resources provide an overview of the outpatient administration process, procedures, and requirements:

- **The U.S. Government's Monoclonal Antibody Therapeutics Playbook:** https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook_25Feb2021.pdf
- **The Lilly Bamlanivimab and Etesevimab Together Antibody Playbook (March 2021):** https://www.covid19.lilly.com/assets/pdf/bam-ete/lilly-antibodies-playbook.pdf
- **The Regeneron REGEN-COV™ (Casirivimab with Imdevimab) EUA Guidebook (February 2021), developed with the National Infusion Center Association:** http://regeneroneua.com/Content/pdf/treatment-covid19-eua-guide-book.pdf



Talking with Patients about Monoclonal Antibodies for COVID-19: Tips and Frequently Asked Questions

Early treatment with monoclonal antibodies may prevent your high-risk COVID-19 patients from progressing to more severe disease or hospitalization.

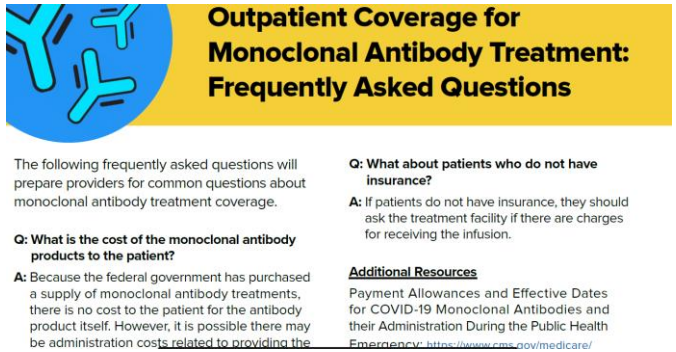
Tips for Talking with High-Risk Patients about Monoclonal Antibody Treatment

- Talk with your patients about receiving

Frequently Asked Patient Questions

Q: Why should I seriously consider monoclonal antibody treatment?

A: If you are high risk, develop mild to moderate symptoms, and test positive for COVID-19, early treatment with monoclonal antibodies may prevent progressing to more severe disease



Outpatient Coverage for Monoclonal Antibody Treatment: Frequently Asked Questions

The following frequently asked questions will prepare providers for common questions about monoclonal antibody treatment coverage.

Q: What is the cost of the monoclonal antibody products to the patient?

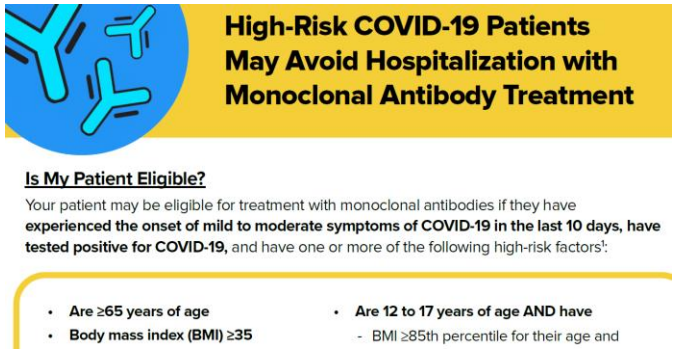
A: Because the federal government has purchased a supply of monoclonal antibody treatments, there is no cost to the patient for the antibody product itself. However, it is possible there may be administration costs related to providing the

Q: What about patients who do not have insurance?

A: If patients do not have insurance, they should ask the treatment facility if there are charges for receiving the infusion.

Additional Resources

Payment Allowances and Effective Dates for COVID-19 Monoclonal Antibodies and their Administration During the Public Health Emergency: https://www.cms.gov/medicare/

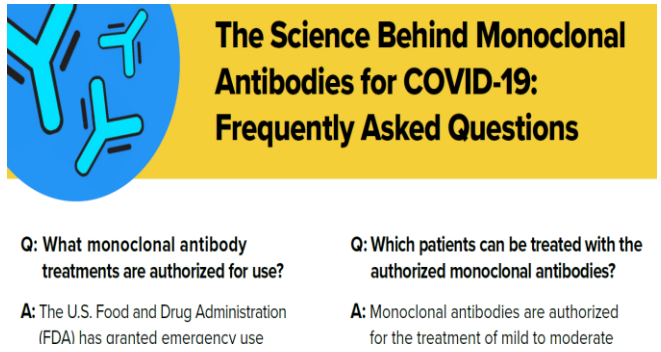


High-Risk COVID-19 Patients May Avoid Hospitalization with Monoclonal Antibody Treatment

Is My Patient Eligible?

Your patient may be eligible for treatment with monoclonal antibodies if they have **experienced the onset of mild to moderate symptoms of COVID-19 in the last 10 days, have tested positive for COVID-19,** and have one or more of the following high-risk factors[1]:

- **Are ≥65 years of age**
- **Body mass index (BMI) ≥35**
- **Are 12 to 17 years of age AND have**
  - BMI ≥85th percentile for their age and



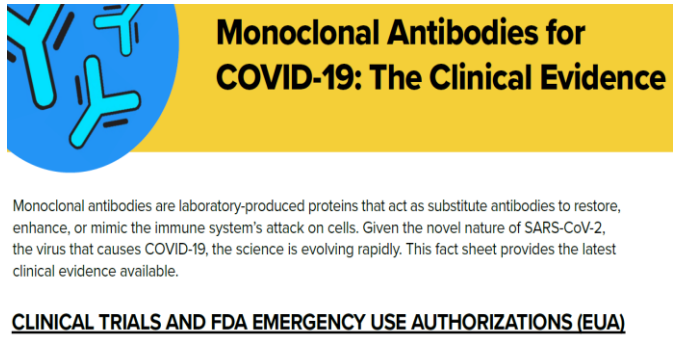
The Science Behind Monoclonal Antibodies for COVID-19: Frequently Asked Questions

Q: What monoclonal antibody treatments are authorized for use?

A: The U.S. Food and Drug Administration (FDA) has granted emergency use

Q: Which patients can be treated with the authorized monoclonal antibodies?

A: Monoclonal antibodies are authorized for the treatment of mild to moderate



Monoclonal Antibodies for COVID-19: The Clinical Evidence

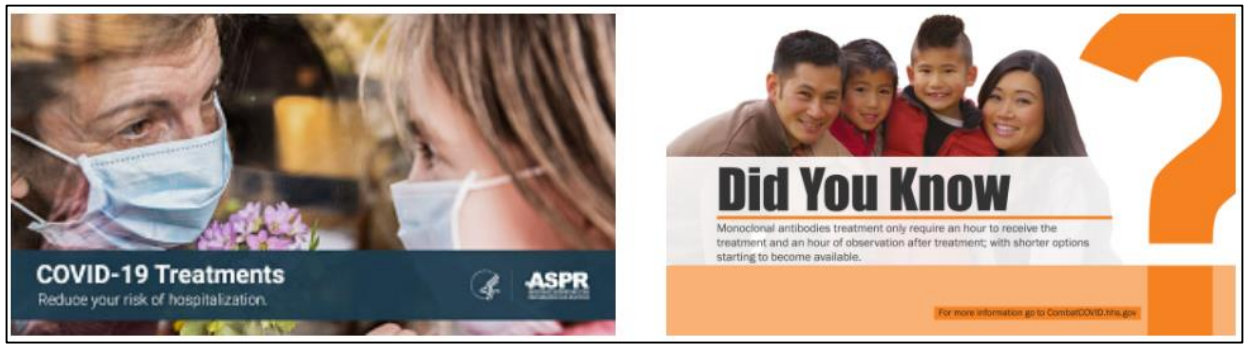
Monoclonal antibodies are laboratory-produced proteins that act as substitute antibodies to restore, enhance, or mimic the immune system's attack on cells. Given the novel nature of SARS-CoV-2, the virus that causes COVID-19, the science is evolving rapidly. This fact sheet provides the latest clinical evidence available.

CLINICAL TRIALS AND FDA EMERGENCY USE AUTHORIZATIONS (EUA)

Fact sheets are available at https://combatcovid.hhs.gov/hcp/resources
Please share with the providers in your network.

COMBATCOVID

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=MYkjIfde3VI
    - 'Monoclonal antibodies': 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

Upcoming webinars

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
- **Zoom link:** https://bit.ly/3rfRv4E
  - 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**
- **HHS Website: 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-90afb7a3cd1d**
- **Direct Ordering Link via ABC: https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8**
- **Treatment Site locator tool https://protect-public.hhs.gov/pages/therapeutics-distribution**
- **Reach out to the Federal COVID-19 Response Team:** COVID19Therapeutics@hhs.gov

Thank you!