# Utilizing Monoclonal Antibody Therapeutics in Long-term Care Facilities as a Tool to Prevent and Mitigate COVID-19

## November 2, 2021

# Overview

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Commonwealth of Massachusetts
Department of Public Health

# *Updated* DPH Guidance: 10/29/21

**Massachusetts Department of Public Health**
**Guidance for Allocation of COVID-19 Monoclonal Antibody Therapeutics to Health Care Providers October 29, 2021**

The U.S. Food and Drug Administration (FDA) has issued emergency use authorizations (EUA) for three monoclonal antibody therapeutics for treatment of early mild-to-moderate COVID-19 in high-risk patients. Two are also available for post-exposure prophylaxis. These three monoclonal antibody therapeutics, REGEN-COV (casirivimab and imdevimab), sometimes known by its manufacturer's name, Regeneron, bamlanivimab and etesevimab, administered together, and sotrovimab are not available through commercial channels but can be requested through federal sources. Each state is being allocated monoclonal antibody therapeutics courses by the federal government based upon the state's COVID-19 case prevalence and hospitalizations as well as the proportion of allocated monoclonal antibody therapeutics administered each week. Each state is responsible for developing an ordering and reporting process for providers to request monoclonal antibody therapeutics courses and report data about courses administered. This is necessary for the state to report required data to the federal government and receive ongoing allocation. This updated guidance shares appropriate use for monoclonal antibody therapeutics, now including sotrovimab, and the process for ordering them from the Department of Public Health (DPH).

I. Authorized use

Under the EUAs, the three monoclonal antibody therapeutics are authorized for the treatment of mild to moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg and who are at

Therapeutic Guidance for HCP: https://www.mass.gov/doc/allocation-of-covid-19-monoclonal-antibody-therapeutics-to-health-care-providers-0/download

**NEW:** DPH has transitioned from an order form to a web-based survey link. **Providers should use this survey to report required data and to make mAb requests.** The survey can be accessed here: https://arcg.is/1emibf

**For urgent Requests also email:** covid19.resource.request@mass.gov

# DPH Guidance

- The U.S. Food and Drug Administration (FDA) has issued Emergency use authorization (EUA) for monoclonal antibody therapeutics for treatment of early mild-to-moderate COVID-19 in high-risk patients.
- Each state is being allocated monoclonal antibody therapeutics by the federal government based upon the state's COVID-19 case prevalence and hospitalizations as well as the proportion of allocated monoclonal antibody therapeutics administered each week.

CMS Monoclonal Antibody COVID--19 Infusion https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion

# Indications

- Monoclonal antibody therapeutics (mAb) are authorized for the treatment of mild to moderate COVID-19 in adult and pediatric patients with positive SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

- mAb should be administered as early as within 72 hours of a positive SARS-CoV-2-specimen collection date and no later than 10 days after symptom onset in accordance with the EUA.

- These products are not authorized for use in patients requiring hospitalization due to COVID-19 or who require supplemental oxygen (or increase in supplemental oxygen for those requiring chronic oxygen therapy) due to COVID-19.

- **Two products, are also approved under EUA for post-exposure prophylaxis.**

# Post-Exposure Prophylaxis

EUA for two products includes use as post-exposure prophylaxis in those who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:

- Not fully vaccinated 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) and
- Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC or who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

# Available Products and Indication(s)

- bamlanivimab and etesevimab (Eli Lilly)
  - Treatment AND PEP
    - IV administration only
- casirivimab and imdevimab (Regeneron)
  - Treatment AND PEP
    - IV administration and **can be give subcutaneously**
- Sotrovimab (GSK)
  - Treatment ONLY
    - IV administration only

# Advance Preparation

- Have standing orders ready in advance for all residents
  - Consider IV versus SC option
    - If IV is not possible or will lead to delay, consider SC
  - Ensure Medical Director is on board
- Obtain consent from residents/families in advance-before an outbreak or exposure occurs
- Communicate in advance, with pharmacy regarding necessary supplies
  - Needles, syringes, and tubing (if IV admin)
    - Include needles for drawing up medication as well as administration
  - Rescue medication kits
- Provide education for staff on the indications for use and administration of mAb.

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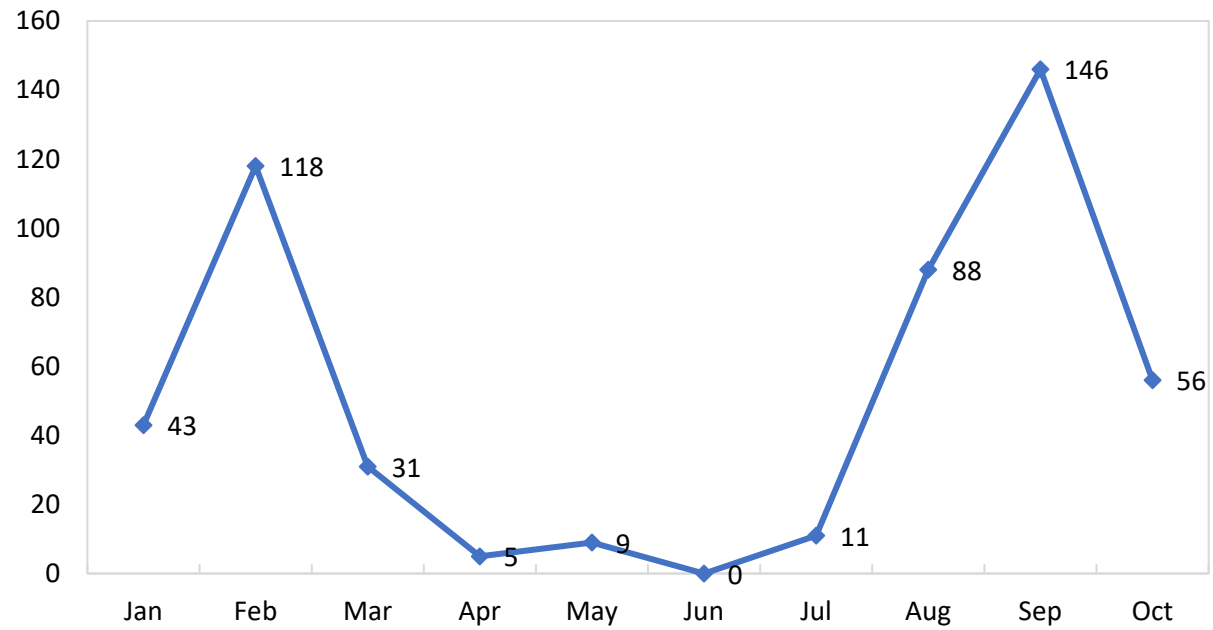
# MA Experience to Date
# October 2021

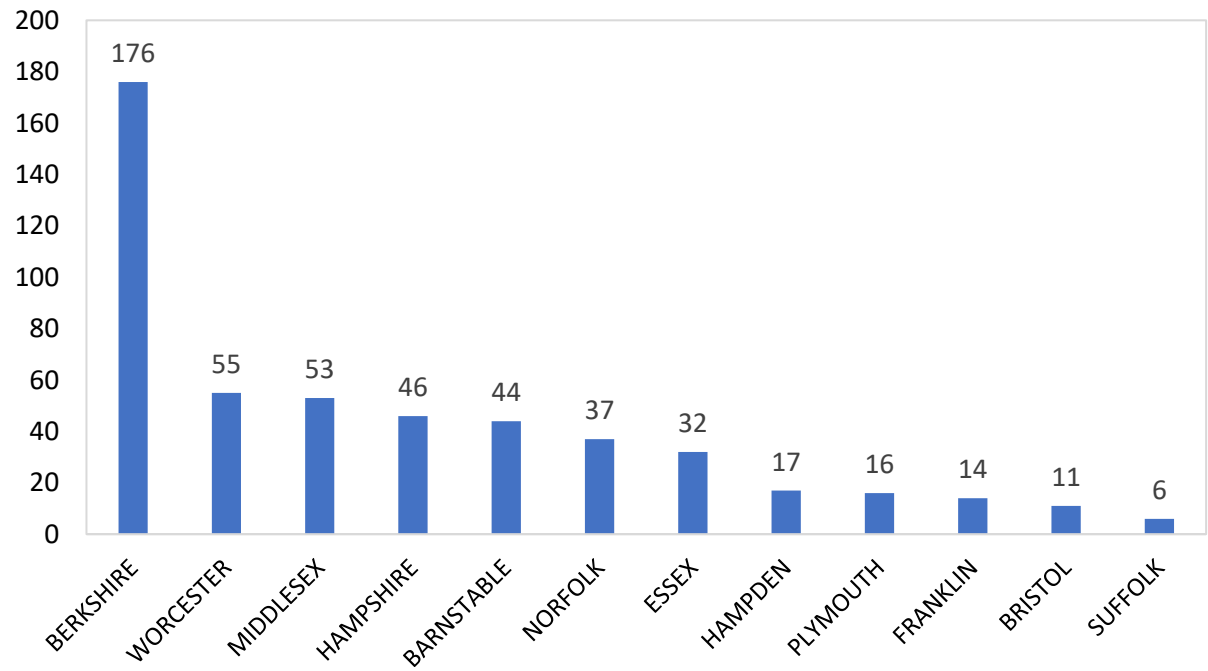
- As of 10/19/2021, **52** long term care facilities reported **507** COVID-19 monoclonal antibody infusions since January. **September** was the peak month followed by February; however, many doses have been administered in just the last week.

- **Berkshire** county has reported the most COVID-19 monoclonal antibody infusions, **176** infusions at **7** facilities

COVID-19 Monoclonal Antibody Therapeutics Administration by Month (N=507)




COVID-19 Monoclonal Antibody Therapeutics Administration by County (N=507)




Data Source: NHSN, 10/20/2021

# Clinical Considerations

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Massachusetts Department of Public Health

# One Facility's Experience

## Mary Pandolfo, RN

Vice President of Clinical Services

Wingate Healthcare

# FAQs

- How does my facility obtain mAb?

- How long must my resident wait to receive a booster dose after receiving mAb?

- Is it better to provide a booster dose or mAb to an exposed resident?

Thank you for participating.

Questions or Comments?

Please email Melissa Cumming at:
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