



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
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Memorandum

TO: Healthcare Facilities Infusing COVID-19 Monoclonal Antibodies Therapeutics

FROM: Margret Cooke, JD, Deputy Commissioner
Larry Madoff, MD, Medical Director for the Bureau of Infectious Disease and Laboratory Sciences

DATE: April 13, 2021

RE: Updates for Patients Receiving COVID-19 Monoclonal Antibodies Therapeutic Infusions, Bamlanivimab/Etesevimab and REGEN-COV (Casirimab/Imdevimab)

The Massachusetts Department of Public Health (DPH) continues to work with state, federal and local partners to address the outbreak of Coronavirus Disease 2019 (COVID-19), caused by the virus SARS-CoV-2, and we continue to appreciate the essential role you have in responding to this evolving situation.

This guidance replaces and supersedes all previous monoclonal antibodies COVID-19 therapies documents released by DPH. As monoclonal antibodies therapies are now readily available for health care facilities to directly request through pharmaceutical manufacturers, DPH is rescinding Guidance for Allocation of COVID-19 Monoclonal Antibody Therapeutics for Participating Hospitals dated November 27, 2020 and Guidance for Allocation of COVID-19 Monoclonal Antibody Therapeutics in Non-Hospital Settings dated January 13, 2021 which outlined prioritizing patients for administration in an equitable manner in the context of scarcity.

Given the sustained increase in SARS-CoV-2 viral variants in the United States that are resistant to bamlanivimab administered alone, and the availability of other authorized monoclonal antibody therapies that are expected to retain activity to these variants, the U.S. Government,

in coordination with Eli Lilly and Company, stopped the distribution of bamlanivimab alone as of March 24, 2021.

Monoclonal antibody therapies that are currently authorized for use include [bamlanivimab and etesevimab](#), administered together and [REGEN-COV](#).

The monoclonal antibody therapeutics may be used for patients with laboratory confirmed (including rapid antigen test) COVID-19 who do not require hospitalization for COVID-19. Decisions about which eligible patients receive the drugs should be based on the clinical judgement of hospitals and providers, consistent with the clinical parameters and timeframe specified in the EUAs.

Ordering:

Hospitals, long term care facilities, dialysis providers, acute and urgent sites, and infusion sites may request monoclonal antibody therapies through the federal government via AmerisourceBergen at:

<https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>

If facilities require an urgent supply or do not need the minimum order amount, they may complete the attached response form and send to DPH at COVID19.Resource.Request@mass.gov for an allocation.

Reporting:

In an effort to ensure ongoing equitable distribution of monoclonal antibodies therapeutic infusions of bamlanivimab and etesevimab, administered together and REGEN-COV, DPH will continue to monitor data submitted by the infusing healthcare institution. Required data elements as outlined on page 4 of this memo will be reported through the **DPH Healthcare Facility Reporting System (HCFRS)** by **5pm every Friday**.

Questions related to mandatory reporting related to this memorandum should be directed to kerin.milesky@mass.gov, Director for the Office of Emergency Preparedness.

Reporting Instructions: After logging into HCFRS, the user should complete for each therapeutic infusion delivered:

- Create new case
- Select "Enter Intake Report"
- Select "COVID-19 Monoclonal antibody therapeutics" as incident type
- Document the date of transfusion as the "Incident Date"
- Complete the required fields listed below
- Save the intake report
- Select "Submit intake report"

COVID-19 Monoclonal antibody therapeutics Reporting Data Elements

<i>Data Element</i>	<i>Response Options</i>
Age	- Numeric Value
Allocation Pool	- Open Allocation - Live in SVI >50% or municipality with incidence rate in top quartile
Assigned Sex at Birth	- Male - Female - Something else
Body Mass Index	- <35 - ≥35
Employment	- Unemployed - Part-Time/Temporary - Full-Time - Choose not to answer - N/A
Is Patient Hispanic/Latino/Spanish?	- No - Yes - Unknown
Highest Level of Education	- Less than high school diploma - High school diploma - Undergraduate degree or higher
Long-Term Emotional/Learning Disorder?	- Yes - No - Choose not to answer
Physical Disability/Long-Term Health Disorder?	- Yes - No - Choose not to answer
What language does the patient prefer to use when speaking about their health?	- Multiple options - Other - Unknown
Race (Check all that apply)	- Asian - African American - Caucasian - American Indian / Alaska Native - Native Hawaiian or Other Pacific Islander - Other - Unknown

Home Zip Code (SVI Status Proxy) - Five-digit zip code

Therapeutics Referral - Internal
- External

Has the patient ever served in the military? - Yes
- No
- Unknown