



Massachusetts Department of Public Health

Guidance for Allocation of COVID-19 Monoclonal Antibody Therapeutics in Non-Hospital Settings

January 13, 2021

The U.S. Food and Drug Administration (FDA) has issued emergency use authorization (EUA) for two monoclonal antibody therapeutics for treatment of early mild-to-moderate COVID-19 in high-risk patients. Following issuance of the EUAs the federal government has begun to provide doses to states to be administered by intravenous infusion in a monitored healthcare setting. This guidance sets forth expectations for Massachusetts long term care facilities which elect to receive allocations of one of these COVID-19 therapeutics, bamlanivimab.

Bamlanivimab is a monoclonal antibody developed by Eli Lilly and Company that has received EUA from the FDA. Any long term care facility receiving an allocation of bamlanivimab must comply with the applicable terms of the [EUA](#) and authorized [Fact Sheets](#).

The Department of Public Health (DPH or the Department) assembled a Working Group, comprised of infectious disease specialists, emergency physicians, community health center representatives and ethicists to advise on equitable public health strategies to allocate the doses of COVID-19 therapeutics delivered to Massachusetts in the event that there is not sufficient capacity to respond to demand for this scarce resource. To ensure equitable distribution to those most vulnerable to poor outcomes from COVID-19 and communities with the highest incidence of COVID-19, long term care facilities should allocate available doses of bamlanivimab in a manner consistent with this guidance, including:

Among those patients who meet the EUA criteria, prioritize patients age ≥ 65 and those age ≥ 18 with BMI ≥ 35 (Tier 1) over others who meet EUA criteria (Tier 2)

Decisions about which eligible long term care residents receive the drugs should be based on the clinical judgement of the providers, consistent with the terms of the EUA and with this guidance.

Long term care criteria for bamlanivimab use should be as clear, transparent, and objective as possible, and be based on biological factors related only to the likelihood and magnitude of benefit from the medical resources and should at all times minimize inequitable outcomes. Factors that have no bearing on the likelihood or magnitude of benefit, include but are not limited to, race, disability, gender, sexual orientation, gender identity, ethnicity, ability to pay, socioeconomic status, perceived social worth, perceived quality of life, immigration status, incarceration status, homelessness or past or future use of resources. Such factors are not to be considered by providers when making allocation decisions. Given the uncertainty surrounding the benefits and risks of bamlanivimab in treating COVID-19, the decision to treat should be carefully discussed by the healthcare provider with each resident.

I. Criteria for long term care facility to receive allocation

Identified long term care facilities electing to receive allocations of bamlanivimab must submit the Response Form to DPH to confirm their capabilities and capacity to safely perform infusions and agree to equitably deliver bamlanivimab to residents authorized under EUA and consistently with this guidance. Specifically, this includes the capacity and capability:

- To establish infusion capacity for individuals with COVID-19 in accordance with the bamlanivimab EUA;
- To implement the DPH Allocation Framework that selects patients from among those meeting eligibility criteria;
- To establish infusion capacity for individuals with COVID-19 in accordance with all applicable state and federal requirements;
- To report data on a weekly basis to DPH as directed.

Long term care facilities should complete the request form, Appendix A, when they identify residents who meet the infusion criteria outlined in this document and in the EUA and have infusion capacity.

II. Authorized use

Under the EUA, bamlanivimab is authorized for the treatment of mild to moderate COVID-19 in adults 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 high risk for progressing to severe COVID-19 and/or hospitalization.

The criteria for use are specified in the EUA, currently or as it may be updated. Additionally, it is notable that the clinical trials that formed the basis for the EUAs required that bamlanivimab be administered within 72 hours of the time that a positive SARS-CoV-2 sample was sent. It is strongly encouraged that facilities providing this therapy to residents adhere as closely to that as possible, as there are no data for efficacy outside that timeline.

III. Allocation in the event of scarcity

Due to the limited supply and the logistical challenges in establishing infusion centers capable of delivering bamlanivimab, the demand for the drugs may exceed available doses.

a. Clinical prioritization

Tier 1: Patients who are age, ≥ 65 years and patients aged 18 and older with BMI ≥ 35 .¹

¹ This prioritization is based on the fact that age and elevated BMI have both been demonstrated to be associated with poor outcomes including hospitalization, critical illness and death in COVID-19 patients, and the fact that the evidence on which the EUA for bamlanivimab is based suggested increased benefit in patients with these

Tier 2: All other patients eligible under the EUA.

b. Equitable allocation

Given the disproportionate rates of hospitalizations and deaths and the disproportionate impact of COVID-19 on certain communities with high social vulnerability, including long term care residents, and the public health importance of mitigating severity of disease in the hardest hit areas, it is a priority to ensure that socially vulnerable patients receive equitable access to bamlanivimab that mitigates the disproportionate impact.²

Potential barriers to equitable distribution of bamlanivimab include the possibility of bias in identification and referral of patients who may be eligible under the EUA and at highest risk of complications of COVID-19, anticipated difficulty scheduling socially vulnerable patients for infusion appointments, and challenges in obtaining transportation to infusion centers.

Long term care facilities which elect to receive an allocation of bamlanivimab will be expected to operate a delivery system and allocation framework that intends to meet the goal of equitable distribution and will be required to produce regular reporting with relevant metrics. These metrics include the resident's race, ethnicity, age category, preferred language and sex.

IV. Reporting

All sites will be required to report data to DPH on a weekly basis no later than Fridays at 5 PM via the Health Care Facility Reporting System (HCFRS) to allow for identification of barriers to equitable distribution and possible system improvements. Specific instructions may be found in the Therapeutics Data Collection memo dated December 16, 2020.

characteristics. Chen, Peter, et al. "SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19." *New England Journal of Medicine* (2020).

² The prioritization of socially vulnerable patients is based on multiple considerations, including substantially higher risk of hospitalization and death from COVID-19 in these patients and public health considerations that favor mitigating disease in the hardest hit areas. In the state of Massachusetts, for the two weeks ending November 11, 2020, people from a census tract with SVI >50% represented 60.3% of the total COVID-19 cases (and 46% of the population). People from a census tract with SVI > 75% represented 33.2% of the total cases (and 18.7% of the population).