



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 high risk for progressing to severe COVID-19 and/or hospitalization. The EUAs may be found here:

Bamlanivimab and etesevimab: <https://www.fda.gov/media/145802/download>

REGEN-COV: <https://www.fda.gov/media/145611/download>

Sotrovimab: <https://www.fda.gov/media/149534/download>

The criteria for use are specified in the EUAs, currently or as they may be updated. Additionally, it is notable that the clinical trials that formed the basis for the EUAs required that monoclonal antibody therapeutics be administered as early as 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 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.

Post-Exposure Prophylaxis:

Post-exposure prophylaxis with REGEN-COV or bamlanivimab and etesevimab, administered together, is not a substitute for vaccination against COVID-19. REGEN-COV, bamlanivimab and etesevimab, administered together, and sotrovimab are NOT authorized for pre-exposure prophylaxis.

The FDA has authorized an additional use for the COVID-19 monoclonal antibody therapeutic REGEN-COV and bamlanivimab and etesevimab, administered together. Their EUAs have been expanded to include post-exposure prophylaxis (PEP). FDA’s authorization of a therapeutic product for post-exposure prophylaxis is a significant advancement in the COVID-19 response that supplements vaccination for disease prevention.

The new authorization is for post-exposure prophylaxis use in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals 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)

II. Administration

For non-hospitalized treatment the authorized dose of sotrovimab is 500 mg of sotrovimab as a single intravenous infusion. For both non-hospitalized treatment and post-exposure prophylaxis use, the authorized dose of REGEN-COV is 600 mg of casirivimab and 600 mg of imdevimab. For treatment of mild to moderate COVID-19, a single intravenous infusion is strongly recommended; however, subcutaneous injection may be an alternative if infusion is not feasible or would significantly delay treatment. For both non-hospitalized treatment and post-exposure prophylaxis use, the authorized dosage is 700 mg bamlanivimab and 1,400 mg of etesevimab, administered together as a single intravenous infusion.

For post-exposure prophylaxis, REGEN-COV may be administered as either subcutaneous injection or a single IV infusion, i.e., there is no preference for IV administration for post-exposure prophylaxis for this product. For post-exposure prophylaxis, bamlanivimab and etesevimab, administered together, must be administered as a single IV infusion. Please refer to the updated Fact Sheets for full details about dosing and administration:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>

III. Criteria for healthcare providers to receive allocation

Identified healthcare providers electing to request to receive allocations of monoclonal antibody therapeutics must submit data to DPH to confirm their capabilities and capacity to safely perform infusions and agree to equitably deliver monoclonal antibody therapeutics to individuals

authorized under EUA and consistently with this guidance. Specifically, this includes the capacity and capability:

- To establish infusion or administration capacity for individuals with COVID-19 or who have been exposed to COVID-19 in accordance with the monoclonal antibody therapeutics EUAs;
- To establish infusion or administration capacity for individuals with COVID-19 or who have been exposed in accordance with all applicable state and federal requirements;
- To report aggregate data on a weekly basis to DPH as directed.

IV. Clinical Prioritization

There is a potential for limited supply of monoclonal antibody therapies and so the demand for the drugs may exceed available courses.

To ensure equitable distribution to those most vulnerable to poor outcomes from COVID-19 and communities with the highest incidence of COVID-19, providers should allocate available doses of monoclonal antibody therapeutics 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)
- Within tiers, priority should be given to individuals who are not fully vaccinated or to those less likely to have mounted an adequate immune response to vaccination (e.g., due to immunocompromise).
- Priority should be given to those requiring treatment of symptomatic COVID-19 over those for whom PEP is indicated.

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

Provider criteria for monoclonal antibody therapeutics 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.

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 monoclonal antibody therapies that mitigates the disproportionate impact.¹

Potential barriers to equitable distribution of monoclonal antibody therapies 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.

Providers that elect to request an allocation of monoclonal antibody therapies 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 aggregate metrics.

V. Ordering and Reporting

As part of the weekly ordering process, all providers will be required to report inventory data, the number of courses administered in the previous week, and other requested aggregate data as directed by the Office of Preparedness and Emergency Management (OPEM) to allow for identification of barriers to equitable distribution and possible system improvements. Fulfillment of any future requests will be dependent on the provider complying with this reporting requirement.

Providers should use this [survey](#) to report required data and to make monoclonal antibody therapeutics requests. The survey can also be accessed by entering this link into your web browser <https://arcg.is/1emibf>. Reporting and requests are due by 3 p.m. each Wednesday. DPH will notify providers if their requested number of courses cannot be fulfilled as soon as possible.

Providers that identify that they need an urgent or unanticipated allocation of monoclonal antibody therapies due to newly identified COVID-19 clusters or outbreaks should also notify covid19.resource.request@mass.gov as soon as possible and DPH will make every effort to address this request in a timely manner.

HHS provides this directory of mAb infusion sites:
<https://protect-public.hhs.gov/pages/therapeutics-distribution>

¹ 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).