

# Interim Ethical Guidance for Monoclonal Antibody Treatment Administration

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This document was collectively developed by the Minnesota Department of Health (MDH) and the Minnesota COVID Ethics Collaborative (MCEC) co-led by Debra DeBruin, Ph.D., from the University of Minnesota, Center for Bioethics and Susan M. Wolf, J.D., from the University of Minnesota Consortium on Law and Values in Health, Environment & the Life Sciences.

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## Introduction

This guidance should be used for both Eli Lilly Bamlanivimab and Regeneron Casirivimab and Imdevimab monoclonal antibodies (mAbs).

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) on Nov. 9, 2020, to permit the emergency use of “the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.”<sup>1</sup> On Nov. 21, 2020, a similar EUA was issued to permit the emergency use of “casirivimab and imdevimab, administered together, for the treatment of mild to moderate coronavirus disease 2019 (COVID-19)” in adult and pediatric patients.<sup>2</sup>

Notably, neither of these EUAs authorize the administration of either therapy for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19.<sup>2,3</sup>

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<sup>1</sup> US Food and Drug Administration (FDA). Nov. 9, 2020. Letter to Christine Phillips, PhD, RAC, Eli Lilly and Company. <https://www.fda.gov/media/143602/download>

<sup>2</sup> US Food and Drug Administration (FDA). Nov. 21, 2020. Letter to Yunji Kim, PharmD, Regeneron Pharmaceuticals. <https://www.fda.gov/media/143891/download>

<sup>3</sup> FDA. Nov. 9, 2020. FDA News Release: Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibody for Treatment of COVID-19. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19>

The U.S. government has secured supplies of these antibody therapies for distribution to states. Shipments are expected weekly. Allocation and administration of these therapies are time-sensitive, as both EUAs specify that infusions be administered as soon as possible after positive COVID-19 test result and within 10 days of symptom onset.<sup>4</sup> Health care providers are expected to follow the guidance outlined in the EUAs to equitably and ethically distribute this treatment. The State is providing this tool to assist health care partners in accurately screening positive COVID-19 patients to see if they are eligible to receive treatment.

For more information, including provider fact sheets, reference [Eli Lilly: Bamlanivimab for COVID-19 \(https://www.lilly.com/news/media/media-kits/bamlanivimab-covid19\)](https://www.lilly.com/news/media/media-kits/bamlanivimab-covid19) and FDA news release for Casirivimab and Imdevimab at [Coronavirus \(COVID-19\) Update: FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19 \(https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19\)](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19).

## Allocation for administration

Due to the inclusivity of the EUAs for mAbs, many individuals will qualify to receive it. *In the first week or two, demand is expected to exceed supply of this treatment; therefore, facilities should assume supply is insufficient.* In subsequent weeks, facilities should assess whether supply is insufficient as described below.

Patients who are terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice) are only eligible if mAbs are considered to be in sufficient supply (e.g., when the number of doses received meets or exceeds MDH's projection of need). MDH will notify facilities whether mAbs are in sufficient or scarce supply at the time of each week's shipment.

Due to the time sensitivity of the efficacy of this treatment, MDH and MCEC recommend facilities develop plans to administer the treatment 7 days/week.

At this time, MDH and MCEC recommend the following distribution to qualified individuals to promote equity and fairness.

**Facilities should monitor how many qualified individuals they have each week. If the number of qualified individuals is equal to or less than the number of doses they receive, the resource is not considered to be scarce and all qualified individuals should receive the medication.**

### **If supply is insufficient to meet demand:**

1. If a facility receives more doses than the days they are administering mAbs, we recommend evenly distributing the allotment over that number of days.
  - For example, if location received 150 doses for the week and will administer the treatment 7 days/week, they should divide by 7 and allocate 21-22 doses/day to eligible individuals.

<sup>4</sup> FDA. Nov. 9, 2020. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab, p.3. <https://www.fda.gov/media/143603/download>

- This will promote equity by reserving doses for individuals who test positive later in the week.
2. If your facility has the ability to randomize among eligible individuals each day, do so to balance supply to demand (i.e., if demand is three times supply either predicted or demonstrated, randomize 1/3 of patients to treatment).
  3. If you cannot randomize, then first come, first served is allowable each day for the interim, until further guidance from MDH and MCEC is issued.
    - Recognizing not all facilities will have the ability to randomize among eligible individuals, first come, first served is adequate for the time being.
    - First-come, first-served often puts certain populations at a disadvantage, including the uninsured, those without a primary care provider, English as a Second Language, lower socioeconomic status, etc.
  4. Based on EUAs, at this time MDH and MCEC do not recommend allocation based on clinical tiers.
    - Evidence of differential risk / benefit when these factors are used in combination is currently lacking.
  5. Roll unused daily doses into the next day.
    - Not all allotted daily doses might be assigned to qualified individuals each day. If there are leftover doses, they should be added to next day for distribution. Continue to rollover the unassigned doses until the end of the week.
    - Upon receipt of a new shipment, unused doses from the previous week can be added to the new shipment and a new daily allotment can be calculated for the upcoming week.
  6. Facilities should work with their health care coalition (HCC) region to share supply within the region as needed.
    - Doses are allocated to HCC regions, therefore, all doses should remain in the region.
    - Doses should not be shared hospital to hospital in different regions.
    - Sufficient communications with HCC leadership is expected from all participating health care facilities.



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