Monoclonal antibody therapy use for COVID-19 in Oregon FAQs
(Updated 12-8-2020)

Q1. What are the monoclonal antibody therapies?
A1. Bamlanivimab and casirivimab+imdevimab are monoclonal antibodies that are still being studied. Early clinical trials showed that these antibody therapies may reduce the likelihood of hospitalization in symptomatic outpatients who are early in the course of their illness, high risk and COVID-19 test positive. The FDA has authorized the emergency use of these therapies for COVID-19 under an Emergency Use Authorization (EUA).

Q2. What is an Emergency Use Authorization?
A2. Normally, the FDA requires drug companies to complete careful testing to prove that a drug is safe and effective. Emergency Use Authorizations (EUA) are the FDA’s way of giving permission to use drugs that haven’t been proven safe or effective yet. EUAs are given during emergencies when no other approved, effective drugs are available.

In order to receive an EUA, two major requirements must be met:

1. A drug must meet certain criteria for safety, performance, and labeling.
2. There are no adequate, approved, or available alternatives.

Q3. Can monoclonal antibody therapies be used to treat anything else?
A3. No. Emergency Use Authorizations are only given for specific uses. Bamlanivimab has only been given an EUA to treat certain COVID-19 patients.

Q4. Are monoclonal antibody therapies approved by the FDA to treat COVID-19?
A4. No. Both products are investigational monoclonal antibodies. They are not currently FDA-approved to treat or prevent any diseases, including COVID-19. The FDA has authorized the emergency use of these monoclonal antibodies for COVID-19 under an Emergency Use Authorization (EUA). However, there are no FDA-approved medicines to treat COVID-19 in outpatients (patients in ambulatory or observation care).
Q5. Should I use monoclonal antibodies?

A5. Currently, the Oregon Health Authority is neither recommending nor discouraging the use of monoclonal antibodies for the treatment of COVID-19. The drug has not yet been approved by the FDA for the treatment of any condition but the FDA’s Emergency Use Authorization (EUA) permits clinicians to use monoclonal antibody therapies when they believe it to be potentially beneficial to the patient. The decision to treat a patient with either of these therapies should be approached through shared decision-making with the patient or legally authorized health care representative.

Q6. Will Oregon receive additional doses of monoclonal antibodies?

A6. The Oregon Health Authority anticipates additional allotments in the future, although the amount and timing are unknown.

Q7. How much monoclonal antibody therapies did Oregon receive?

A7. The Oregon Health Authority has received and will continue to receive weekly allotments of both bamlanivimab and casirivimab+imdevimab through December 2020.

Q8. Who can get monoclonal antibody therapies?

A8. Per the FDA’s Emergency Use Authorization, providers may only give bamlanivimab or casirivimab+imdevimab to their patients if the patient is an outpatient with mild to moderate COVID-19 disease. You can find the full criteria under the EUA letters for each product:

- FDA letter of emergency use authorization (EUA) for bamlanivimab
- FDA letter of emergency use authorization (EUA) for casirivimab+imdevimab

Resources:

- Oregon’s Federal bamlanivimab and casirivimab+imdevimab casirivimab+imdevimab Allocation: Prioritization/Distribution Approach
- FDA Fact Sheets for Patients and Parent/Caregivers – Emergency Use Authorization of bamlanivimab and casirivimab+imdevimab For Coronavirus Disease 2019 (COVID-19)
- FDA Frequently Asked Question on the Emergency Use Authorization for bamlanivimab and casirivimab+imdevimab

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