Monoclonal antibody EUA Information and Hospital Allocation

Information in this document changes regularly. Make sure to revisit Oregon COVID-19 Updates page for updates.

Background

In November, 2020, the U.S. Food and Drug Administration (FDA) announced that it issued an Emergency Use Authorizations (EUA) to permit the emergency use of the unapproved products bamlanivimab (LY3819253) and Casirivimab and Imdevimab for treatment of COVID-19.1 Bamlanivimab is a single-target monoclonal antibody targeted against the spike protein of the SARS-CoV-2 virus that inhibits viral entry into human cells. Casirivimab and Imdevimab is a cocktail of two monoclonal antibodies with two different targets on the virus. They are both investigational products and currently do not have FDA approval for any indication. The FDA has issued Fact Sheets for health care providers and patients regarding the EUA for both therapies.

Effectiveness Data

For information about clinical trials that are testing the use of these drugs for the treatment of COVID-19 see www.clinicaltrials.gov.

Bamlanivimab

The EUA issued by the FDA for bamlanivimab states that “based on the totality of the scientific evidence available to date, it is reasonable to believe that bamlanivimab may be effective for the treatment of mild to moderate COVID-19 in certain high-risk patients as specified in this Fact Sheet.” According to a November 9, 2020, FDA news release, “While the safety and effectiveness of this investigational therapy continues to be evaluated, bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo”. There was a reduction in the rate of emergency department visits combined with hospitalization in the placebo group compared to the pooled treated groups (6.3% vs. 1.6%).

1 The emergency use authorization (EUA)s for bamlanivimab and casirivimab+imdevimab.
Casirivimab+imdevimab

The EUA issued by the FDA for casirivimab+imdevimab states that “based on the totality of scientific evidence available to FDA, it is reasonable to believe that casirivimab and imdevimab, administered together, may be effective in treating mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and that, when used under the conditions described in this authorization, the known and potential benefits of casirivimab and imdevimab outweigh the known and potential risks of such products.” In a clinical trial of patients with COVID-19, casirivimab and imdevimab, administered together, were shown to reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo. A lower proportion of subjects treated with casirivimab and imdevimab had COVID-19 related MAVs (2.8% for combined treatment arms vs 6.5% placebo).

Treatment Course

The treatment course of both monoclonal therapies is a single dose administered within 10 days of COVID-19 symptom onset in adults and children greater than 12 years of age and weighing over 40kg. Recipients must have a positive COVID-19 test and mild to moderate COVID-19 disease. Patients hospitalized due to COVID-19, or with COVID-19 disease requiring oxygen administration or increase in oxygen requirements in those with baseline oxygen requirements, are not eligible for treatment under the EUA.

The Fact Sheets for Healthcare Providers outline the following high-risk patient groups as eligible for treatment with both products:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
  - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR
  - neurodevelopmental disorders, for example, cerebral palsy, OR
- a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
- asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

- There are insufficient data on the use of these drugs in patients who are beyond 10 days since their symptom onset.

For additional information on the treatment guidelines for COVID-19 with these therapies please visit the fact sheets for Healthcare providers:

Oregon Distribution of Monoclonal Antibody therapies
Oregon began receiving allotments of donated antibodies starting in November 2020. OHA has begun allocating a subset of initial doses to facilities and providers with ready workflow and capacity to perform the infusion of this therapy, while it continues to review available data to ensure the therapy is distributed in an equitable manner. These shipments will be made directly to hospitals by the distributor, AmerisourceBergen. It is unknown when the donated doses from the federal government will stop.

Contraindications to use
Treating providers should review the EUA and Fact Sheets for Healthcare Providers before prescribing these therapies with attention to the following contraindications:

- Patient hypersensitivity to the medication
- Patients with the following conditions:
  - who are hospitalized due to COVID-19, OR
  - who require oxygen therapy due to COVID-19, OR
  - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

Decision to treat
- 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. Providers should review the Fact Sheets for Health Care Providers: Emergency Use Authorization (EUA).
- As required by the federal government, the patient or legally authorized health care representative must be given, in their primary language, the Fact Sheet for Patients and Parent/Caregivers:
• The patient or legally authorized health care representative must be given all the information necessary to make an informed choice, including information about the potential risks and benefits of the treatment.

• Written or Verbal consent must be documented in the patient’s chart, reflecting that the associated potential risks and benefits were discussed with the patient or legally authorized health care representative.

• The patient or legally authorized health care representative must have interpreter access to ensure that all information provided is available in the patient’s primary language, including ASL if needed, and that all written documents are appropriately translated. The patient or legally authorized health care representative should be readily provided the option of consultation with a community health worker or other trusted community representative.

Equity Considerations
The distribution and use of the investigational drugs must take into consideration the historical consequences for people of color and individuals with disabilities who have been impacted by lack of disclosure related to experimental drugs, procedures and testing. The distribution and use of these therapies should include a focus on health equity.²

Treatment decisions should NOT consider or be based upon:

• Race, ethnicity, gender, gender identity, sexual orientation or preference, religion, citizenship or immigration status, or socioeconomic status;

• Ability to pay;

• Age as a criterion in and of itself;

• Disability status or comorbid condition(s) as a criterion in and of itself;

• Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis)

• Judgments that some people have greater “quality of life” than others;

• Judgments that some people have greater “social value” than others.

Document accessibility: For individuals with disabilities or individuals who speak a language other than English, OHA can provide information in alternate formats such as translations, large print, or braille. Contact the Health Information Center at 1-971-673-2411, 711 TTY or COVID19.LanguageAccess@dhsoha.state.or.us

2 Oregon Health Authority’s definition of health equity: Oregon will have established a health system that creates health equity when all people can reach their full health potential and well-being and are not disadvantaged by their race, ethnicity, language, disability, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances. Achieving health equity requires the ongoing collaboration of all regions and sectors of the state, including tribal governments to address:

• The equitable distribution or redistributing of resources and power; and

• Recognizing, reconciling and rectifying historical and contemporary injustices.