

COVID antivirals

In November 2020, the FDA issued Emergency Use Authorizations for the use of two monoclonal antibody products – bamlanivimab and casirivimab+imdevimab – for the treatment of test-confirmed COVID-19 positive patients (adults and children aged greater than 12 years of age and >40kg) with mild to moderate disease. The EUA only includes the treatment of non-hospitalized COVID-19 patients with the high-risk factors including:

- Age > 65 years
- Obesity with BMI > 35 and
- High risk conditions including: diabetes, chronic kidney disease, coronary artery disease, hypertension and others

Full eligibility criteria are available below in the Fact Sheets for Healthcare Providers for each product.

If you are interested in providing this therapy to your community and have the necessary staff and space, please complete the [survey link](#) for the Oregon Health Authority to understand better your capacity and your ability to treat regional community members.

Monoclonal antibodies should be refrigerated and administered by trained personnel and administered within the first 10 days after symptom onset in test-confirmed cases only. Additionally, the requirements of the EUA include that they be administered in settings where providers will be able to monitor for severe side effects including anaphylaxis and can activate the emergency medical services (EMS) as necessary.

The Oregon Health Authority has received small initial shipments of both products and plans to distribute these, and future doses, to providers statewide who are interested and able to provide the needed infusion and monitoring services. The allocation will also consider the following:

- Geographic equity
- Expanded access for those counties with highest rates of bed capacity limitations due to hospitalization for COVID-19 disease
- Expanded access for those counties with highest case-rates (cases/100,000)

Note: There is a limited supply of bamlanivimab and there is not guarantee that

The considerations for distribution of this drug include:

- Space: Dedicated space to treat COVID-19 positive patients with appropriate precautions at facilities equipped to provide infusions
- Refrigeration: required at 2-8 degrees.
- Supplies: Simple IV supplies. Can be given by gravity or pump.

- Staff: Nurse, IV tech with support from physician and pharmacist.
- Scheduling: infusion time is 1-hour, plus an additional 1-hour post-infusion observation period is required.
- Reporting: required for adverse events
- Billing/reimbursement: once commercially available, there could be significant costs for purchasing and administration. While the product is available at no cost in this period, the Medicare payment rate for the infusion of the bamlanivimab product, will be \$309.60. Additional details found on [Medicare Antibody Infusion Program Instruction](#).

Note: Supplies of these therapies are low at this time. Unfortunately, participation in the survey does not guarantee that any particular practice or provider will be able to access the treatment.

Please contact OHA at ORES8.LogisticsChiefs@dhsosha.state.or.us with any questions.

Resources (Bamlanivimab – Eli Lilly and Co.)

- [FDA letter of emergency use authorization \(EUA\)](#)
- [fact sheet for healthcare providers](#)
- [fact sheet for patients, parents and caregivers \(English\)](#)
- [fact sheet for patients, parents and caregivers \(Spanish\)](#)
- [Frequently asked questions](#)
- [Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction](#)
- [Operation Warp Speed Stakeholder Update](#)

Resources (Casirivimab+imdevimab – Regeneron pharmaceuticals)

- [FDA letter of emergency use authorization \(EUA\)](#)
- [Fact sheet for healthcare providers](#)
- [Fact sheet for patients, parents and caregivers \(English\)](#)
- [Fact sheet for patients, parents and caregivers \(Spanish\)](#)
- [Regeneron Dear Healthcare Provider Letter](#)
- [Frequently asked questions](#)
- [CMS Monoclonal Antibody for COVID-19 Infusion Page](#)

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