



# Frequently Asked Questions for Providers: Monoclonal Antibody (mAb) Therapies for COVID-19

COVID-19 treatments known as monoclonal antibodies have the potential to save lives and relieve the burden on our nation's health care system. [Monoclonal antibody](#) therapies are now available in subcutaneous in addition to intravenous formulation.

## General information:

### Q: How do monoclonal antibodies work?

Monoclonal antibodies mimic our immune system's response to SARS-CoV-2 (the infection that causes COVID-19) and are available to eligible, non-hospitalized patients 12 years and older with high risk of progressing to severe COVID-19 or being hospitalized.

### Q: Who is eligible to receive treatment with mAbs?

People ages 12 and older and who weigh more than 40kg/88lbs who:

- Have tested positive for COVID-19
- Are experiencing mild or moderate symptoms of COVID-19
- Had first symptoms within the last 10 days
- Are considered high risk for going into the hospital due to age (more than 65 years old), weight, pregnancy, immunosuppressive disease or treatment, or some other chronic conditions. See list for [casi/imdev](#), [bam/ete](#) and [sotrovimab](#).

### Q: Who is eligible to receive post-exposure prophylaxis with monoclonal antibodies?

People ages 12 and older, weighing more than 40 kg/88lbs, who are exposed or at high risk for exposure (such as in congregate settings) and are:

- Incompletely vaccinated - i.e. unvaccinated or partially vaccinated
- Fully vaccinated but expected not to have as strong an immune response because of immunocompromising illness or being on immunosuppressive medications.

## Q: Who should give this therapy?

Oregon Health Authority (OHA) encourages all providers to offer monoclonal antibody treatment, in IV and/or SQ forms, to appropriate high-risk patients with COVID-19 infection or exposure, to reduce the risk of hospitalization and severe disease. Like vaccination, subcutaneous administration of mAb can be offered by any qualified provider in Oregon, including pharmacists.

## Q: Is monoclonal antibody therapy available in Oregon?

Yes, providers have been administering this treatment in Oregon. In mid-September, the federal government announced a new process for distributing mAb products to providers. Health and Human Services (HHS) will now provide allocations through the state, rather than providers ordering directly from the distributor, Amerisource Bergen. For more information, visit

<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf>.

## Q: Where can I get more information on using monoclonal antibody treatments?

Visit <https://www.oregon.gov/oha/covid19/Pages/monoclonal-antibody-therapy.aspx> or contact OHA with questions: [ORES8.LogisticsChiefs@dhs.oha.state.or.us](mailto:ORES8.LogisticsChiefs@dhs.oha.state.or.us)

Attend the weekly CDC Federal COVID 19 Response: Monoclonal Antibodies Office hours on Tuesdays and Thursdays, 11 am-noon PT or the 101 Webinar for new sites and health administrators, 9-10 am PT every other Friday starting Oct. 1. Please email [COVID19Therapeutics@hhs.gov](mailto:COVID19Therapeutics@hhs.gov) to request Zoom links for these webinars.

## Efficacy:

### Q: Is monoclonal antibody treatment effective in fighting COVID-19?

When used for treatment of mild to moderate COVID-19, [Casirivimab/Imdevimab](#) (casi/imdev) reduced the risk of hospitalization by 50% in clinical trials leading to authorization. Casi/imdev has been shown to reduce the risk of symptomatic COVID-19 by 81% when used as post-exposure prophylaxis.

[Bamlanivimab/Etesevimab](#) (bam/ete) reduced the risk of hospitalization by 70% in clinical trials, leading to authorization.

[Sotrovimab](#) reduced the risk of hospitalization by 79% compared to placebo in trials leading to authorization.

### Q: What brand of mAb should we use during the surge caused by the delta variant?

Several therapies have demonstrated effectiveness against the delta variant of COVID-19.

The [Emergency Use Authorization \(EUA\)](#) for casirivimab/imdevimab was updated in two important ways in July 2021. First, it is now authorized for post-exposure

prophylaxis (PEP) in at-risk individuals in congregate settings. Second, casirivimab/imdevimab can be given subcutaneously (SQ), opening it up to settings where intravenous (IV) administration is not feasible. This is via shots that are very similar to vaccination.

Used together, bamlanivimab/etesevimab are also effective against the delta variant and have recently been authorized for PEP. Given rising interest in mAb therapies, OHA is supporting the use of bamlanivimab/etesevimab and sotrovimab in locations where IV infusion is feasible to conserve restricted supplies of casirivimab/imdevimab for SQ administration.

**Q: Is there a difference in efficacy when giving the mAb treatment subcutaneously (SQ) instead of intravenously (IV)?**

There is a slightly slower onset of action for SQ as opposed to IV. Please refer to the [EUA fact sheet](#).

**Q: How effective are these products against the delta variant specifically?**

Immunologic data demonstrates effectiveness of these products against the delta variant.

## Ordering/shipping/receiving:

On Monday, September 13, 2021, OHA's federal partner, Health and Human Services (HHS) announced mAb administration sites can no longer order mAb directly from the distributor, Amerisource Bergen. Instead, HHS will determine each state's weekly allotment of mAb, and each state will subsequently identify which sites will receive part of that allotment.

Please refer to OHA's "[Instructions for Ordering and Receiving Monoclonal Antibody Therapies](#)" for details.

## Administering and access:

**Q: How can mAb SQ injections improve access beyond offices that can provide infusions?**

SQ injections can improve access by allowing sites and facilities to provide these treatments without requiring additional qualified staff and workflows needed for IV. Additionally, many more outpatient settings have routine workflows in place to provide SQ medications, such as vaccinations.

**Q: Is it possible to administer the monoclonal antibody treatment on a large scale similar to the way vaccines were administered at mass-vax events?**

Not at this time. Staffing challenges are present in many healthcare facilities and settings due to the surge.

**Q: With the shortage in nurse staffing, what are creative ways for health organizations to administer mAb therapies?**

Like vaccines, SQ administration of mAb can be delegated by physicians to other qualified healthcare providers (please refer to licensure, board and regulations for who these may be). As of August 31, 2021, pharmacists can also independently administer by standard protocol.

**Q: Does a doctor have to prescribe the treatment for a patient, or can the patient get the treatment on their own?**

Administering providers will need to assess for eligibility for mAbs (see above for qualifying healthcare providers). Referral requirements vary by system. Patients can also self-refer to pharmacies that participate.

**Q: How can outpatient clinics who are already understaffed provide this lifesaving medication? Will there be support for these clinics from the state?**

SQ administration can be delegated by physicians to other qualified healthcare providers (please refer to licensure, board, and regulations for who these may be). As of August 31, 2021, pharmacists can also independently administer by standard protocol. Staffing challenges are present in many healthcare facilities and settings due to the current surge. OHA is investigating ways to further support staffing.

**Q: Will the subcutaneous version of casir/mdev, REGN-COV2 be widely available for patients age 12 and older?**

OHA is working with clinical partners across the state to increase the number and types of locations able to administer this product, with a focus on supporting access in highly impacted communities.

**Q: Is OHA going to provide model standing orders similar to the vaccine orders?**

OHA and the Board of Pharmacy have designed a SQ administration protocol. [See link here.](#)

**Q: What do we do if a patient changes his/her mind about taking casir/mdev, REGN-COV2 after 1, 2 or 3 SQ injections?**

Stop administration but monitor for 60 minutes.

**Q: What are the CPT codes for administration?**

See the Centers for Medicare & Medicaid Services (CMS) [mAb website.](#)

**Q: Can vaccinated breakthrough cases receive monoclonal antibodies?**

Yes.

**Q: Is mAb recommended for fully vaccinated individuals who test positive and are considered high risk? What about for fully vaccinated individuals who are NOT high risk?**

Monoclonal antibodies are recommended for symptomatic patients who test positive for COVID-19, are still within 10 days of symptom onset, and are at high risk for severe disease, regardless of vaccination status. “At high risk” can refer either to medical risk factors or to groups that have been disproportionately impacted by severe disease.

**Q: Is this therapy utilized when symptom onset is unknown?**

Providers should use their clinical judgment and the best information they can collect regarding symptom onset.

**Q: At what point in the course of the COVID-19 illness should a patient request this treatment?**

The patient must have tested positive for COVID-19 and be within 10 days of their onset of symptoms to be eligible for treatment. The earlier in the course, the better.

**Q: Based on the demographics of reported cases, do you have a sense of what percentage of positive cases may be eligible?**

Unfortunately, we do not have this level of data coming in through our contact tracing or case investigations.

**Q: Could mAb therapy be used in place of vaccination for people not wanting the vaccine?**

No. This cannot be used for pre-exposure prophylaxis.

## Side effects and contraindications

**Q: Are there any negative side effects, contraindications or significant health risks associated with mAb therapy?**

Side effects may include hives, itching, flushing, and fever. More severe reactions can include shortness of breath, chest tightness, nausea, vomiting, and can be consistent with anaphylaxis. Contraindications include severe COVID-19 disease or needing oxygen therapy as a result of COVID-19 disease. Monoclonal antibodies, like other immunologic products, do pose risks for immune system reactions such as the above.

**Q: Are pre-medications recommended for mAb therapy? (Steroids, APAP, or H1 blockers)? If patients have a history of anaphylaxis, should we consider pre-medication? Any specific items for past reactions that we should be more cautious with?**

Pre-medications are not required for IV or SQ administration. Use clinical judgment when administering in patients with higher risk.

**Q: What is the incidence of anaphylaxis?**

Reports of anaphylaxis with the IV product have been in the 0.2% range nationwide. We do not yet have estimates for SQ product.

**Q: Do the mAb therapies interfere with any lab tests (COVID antibody, antigen, or non-COVID tests, blood bank tests, other immunoassays)?**

Monoclonal antibody therapies may interfere with spike protein antibody tests.

**Q: Where can we find a list of the excipients in the vials?**

This is especially for our highly reactive patients. See the [EUA Fact Sheet](#).

**Q: Is it known yet if the mechanism of this therapy is indeed targeting host cell receptors or co-receptors, thereby making the binding sites of host cells unavailable for SARS-CoV-2; if the binding is reversible and after how long?**

Please refer to the [EUA Fact Sheet](#), Section 14.1.

## Monitoring:

**Q: Is line of sight monitoring required? How closely do patients need to be monitored? Can they be left in a room alone but near other clinic activities?**

Line of sight monitoring is not required. Telehealth supervision is adequate. A nurse onsite is recommended to address clinical questions but not required for line of sight monitoring.

**Q: Is the recommendation to obtain q15 minute vitals post injection required for SQ administration?**

There is no q15 minute vitals post-IV or SQ administration required by the EUA. Please monitor for signs and symptoms of adverse reactions, including anaphylaxis.

## Access equity:

**Q: How accessible is this therapy from a health equity perspective?**

OHA is working with clinical partners across the state to increase the number and types of locations able to administer this product with a focus on supporting access in highly impacted communities.

**Q: From a health equity perspective, how are underserved communities, houseless and/or communities where English is not the primary language being made aware of this option? What attempts or techniques are being used to 'get the word out' about the need to access this option during the earliest stages of disease?**

OHA has a goal to end health disparities across our state by the year 2030. To achieve this, we are working to increase outreach and communications in a variety of ways, from provider communications to mainstream media, in multiple languages. We are targeting mAb outreach to highly impacted communities including through our community partners and Federally Qualified Health Centers (FQHCs) across the state, who have been front and center in health equity for many years. OHA has strong relationships with FQHCs throughout Oregon as do our close partners such as the

Oregon Primary Care Association. Aligning our messaging and partnering with them is crucial in supporting health centers to add this to their already full plate. We have also developed communications in multiple languages for radio, television and social media, partnering with organizations that support migrant and seasonal workers, maintaining regular and ongoing Spanish and English-language community partner dialogue, linking to resources in multiple languages, and other efforts.

**Q: How is equitable access to this therapy being centered?**

Eligibility criteria are defined in the EUA and include those communities disproportionately impacted by COVID-19 due to structural racism, systemic inequities and discrimination.

**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 COVID-19 Communications Unit at 1-971-673-2411, 711 TTY or [COVID19.LanguageAccess@dhsosha.state.or.us](mailto:COVID19.LanguageAccess@dhsosha.state.or.us).