

Guidance on the use of Monoclonal Antibody Therapy

Since November 2020, the FDA issued emergency use authorizations (EUA) for the use of investigational SARS-CoV2 monoclonal antibody products. The drugs can be considered for the treatment of high-risk patients with mild to moderate Covid-19, who do not require supplemental oxygen therapy or additional oxygen therapy above their baseline. Since the issuance of the original EUAs, data have emerged on the efficacy of certain monoclonal therapies on circulating variants. Bamlanivimab with and without etesevimab is no longer recommended in the state of California due to a reduction in efficacy against the B.1.427/29 and B.1.351 variants.

The following monoclonal antibody therapy has demonstrated a reduction in hospitalizations and ER visits, has retained efficacy against current circulating variants and is currently available for use.

- a single infusion of casirivimab 600mg/imdevimab 600mg for a total of 1200mg IV over 20 minutes.
- In select circumstances, subcutaneous injection may be used as an alternative (4 injections)

Monoclonal antibodies may be considered if the following criteria are met for patients with mild-moderate symptoms:

- Age ≥ 12 years weighing at least 40 kg
- Not requiring any supplemental O2 or increase from baseline O2 requirements
- SARS-CoV-2 Positive test ≤ 7 days prior
- Symptom onset ≤ 7 days prior
- At least one high-risk criterion

Monoclonal antibodies may also be given to high-risk contacts* who meet the following criteria:

- Age ≥ 12 years weighing at least 40 kg
- Individuals who are considered high risk by the prior EUA criteria who have had a household or workplace exposure to an individual with confirmed SARS-CoV2 for at least 15 minutes and < 6 feet within the 72 hours prior
- Have not been fully vaccinated *OR* have been fully vaccinated and are at risk of a poor immunologic response by virtue of being on immunosuppressive medications, or are transplant recipients, or have a documented hematologic malignancy such as chronic lymphocytic leukemia.

*Please note we have limited space to accommodate high-risk contacts and are almost exclusively focusing on patients with active Covid-19 at this time.

High-risk criteria:

- Age ≥ 65 regardless of medical co-morbidities
- Diabetes
- Immunosuppressive disease or immunosuppressive therapy
- CKD (CrCl < 60 ml/min per Cockcroft-Gault for > 3 months)
- Obesity (BMI ≥ 30) (or if 12-17 BMI $\geq 95^{\text{th}}$ percentile (based on CDC growth chart))
- Neurologic diseases: cerebrovascular diseases, Down Syndrome or other neurodevelopmental disorders, or dementia

Richley M, Rao RR, Afshar Y, Mei J, Mok T, Vijaya T, et al. Neutralizing monoclonal antibodies for coronavirus disease 2019 (covid-19) in pregnancy: a case series. *Obstet Gynecol* 2022;139.

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- Liver disease
- Pregnancy if other risk factors and under maternal fetal medicine consultation (consider checking antibody status)
- Smoking
- Hemoglobin disorders (sickle cell, thalassemia)
- Cardiovascular disease (congenital heart disease, heart failure, CAD, cardiomyopathy, or pulmonary HTN), OR Hypertension
- Chronic lung disease (COPD/emphysema, moderate-severe asthma, CF, pulmonary fibrosis)
- Medical-related technological dependence (tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19)

Individuals coming from a disadvantaged socioeconomic background are considered given their increased risk of mortality. Please note the data on the benefit of this drug remain limited. At this time, there are two pathways whereby patients may obtain these investigational drugs.

- Patients who are in the ER and meet the above criteria but do not meet the criteria for admission may be given casirivimab/imdevimab.
- Other patients may be able to receive the drug at our designated infusion center. We have a centralized process whereby a clinical team will review all outpatients with positive tests who meet criteria. Our team will reach out to the ordering clinician to discuss the treatment with their patients and subsequently place a referral in Care Connect (REFERRAL FOR MONOCLONAL ANTIBODY INFUSION FOR COVID+ PATIENTS [REF1010]).
- Clinicians may also place a referral on their own through Care Connect (REFERRAL FOR MONOCLONAL ANTIBODY INFUSION FOR COVID+ PATIENTS [REF1010]) as long as the criteria are met. Please note each referral will be cross-checked to ensure criteria have been met.
- Referrals for high-risk contacts will be separate from the above referral
- Please review the [patient](#) (Spanish) and [provider](#) fact sheets for casirivimab/ imdevimab. All patients will be given a fact sheet prior to drug administration.

Given that the demand for this therapy may exceed our ability to administer on any given day, the order time stamp and a point system with measures to account for socioeconomic vulnerability will be included in the allocation process. We will review all referrals at 10:30am on each calendar day.

Ongoing trials regarding the efficacy and safety of monoclonal antibodies, including ACTIV-2 as well as other studies, remain open. Please send a message to the COVID Research Pool for more details.

These agents are primarily to be used in the outpatient setting. However, select hospitalized patients may be considered with ID approval.

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