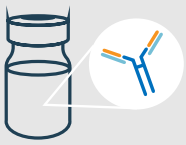
Monoclonal Antibody Therapy

If your patient has COVID-19, monoclonal antibody therapy may be the right treatment option.

When administered to non-hospitalized, high-risk patients as soon as possible after positive viral testing for COVID-19 and within 10 days of symptom onset, monoclonal antibodies **may improve symptoms and reduce risk of hospitalizations and death** associated with COVID-19. Casirivimab + imdevimab is also authorized for post-exposure prophylaxis in select high-risk adult and pediatric populations.

Health care provider referrals are required for treatment and post-exposure prophylaxis.
Talk to your patients about the best treatment options for them.
Remember – this has to be done within 10 days of symptom onset for COVID positive patients.

What are monoclonal antibodies?



Monoclonal antibodies (mAbs) are developed in a laboratory to mimic natural antibodies produced by the immune system. mAbs are administered through intravenous infusion that takes as little as 20 minutes. This therapy is different than convalescent plasma collected from donors.

Who can receive Monoclonal Antibody Therapy under the EUA?

Anyone over 12 years of age weighing more than 40kg (89 pounds) and has one of the following high-risk factors making them more susceptible to severe COVID-19 illness:

- Are older in age (e.g., age > 65 years of age).
- Are obese (Body Mass Index >35) or are overweight (e.g., adults with BMI >25, or if age 12-17, have BMI >85th percentile for their age and gender based on CDC growth charts, Growth Charts - Clinical Growth Charts (cdc.gov))
- Are pregnant
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease or are receiving immunosuppressive treatment
- Have cardiovascular disease or hypertension
- Have chronic lung diseases (chronic obstructive pulmonary disease, moderate to severe asthma, interstitial lung disease, cystic fibrosis, or pulmonary hypertension)
- Have sickle cell disease
- Have a neurodevelopmental disorder (e.g., cerebral palsy) or other condition that confers with medical complexity
- Have a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))

Other medical conditions or factors (e.g., race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of mAb therapy under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: Certain Medical Conditions and Risk for Severe COVID-19 Illness | CDC

For post-exposure prophylaxis: Casirivimab + imdevimab has also received authorization for use as post-exposure prophylaxis of COVID-19 in individuals who are at high risk of progression to severe COVID-19 and are:

- Not fully vaccinated or who are not expected to mount an adequate immune response to complete vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) and
  - Have been exposed to an individual infected with COVID-19 consistent with close contact criteria, or
  - Who are at high risk of exposure to an individual infected with COVID-19 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing home or correctional facility).

Post-exposure prophylaxis is not a substitute for vaccination for COVID-19.

Provider Talking Points:

- There are many sites providing mAb in Michigan currently in at least 37 counties. Current efforts are underway to expand provider sites. **The goal is for 50% of eligible high-risk Michiganders who test positive for COVID-19 to receive the mAb therapy within 10 days of symptom onset.**
- The National Institutes of Health and Infectious Disease Society of America recommend monoclonal antibodies to treat outpatients with mild to moderate COVID-19 who are at risk of clinical progression for severe disease as defined by the EUA.
  - The FDA has authorized the use of COVID-19 monoclonal antibody therapeutic REGEN-COV (casirivimab + imdevimab) for post-exposure prophylaxis in select high-risk populations.
    - The REGEN-COV Emergency Use Authorization (EUA) has been expanded to include post-exposure prophylaxis.
    - Providers should continue to assess patients with high-risk conditions where treatment with monoclonal antibodies is indicated and to identify individuals (e.g., close contacts) who might benefit from post-exposure prophylaxis.
    - Post-exposure prophylaxis is not a substitute for vaccination for COVID-19.
  - Treatment should be started as soon as possible after receiving a positive COVID-19 test result, and within 10 days of symptom onset.
- It is important for clinicians to be aware of the availability of these therapeutics and be proactive in identifying the appropriate patients and providing access.
  - All who test positive for COVID-19 (PCR or antigen) should be screened to see if they meet eligibility for mAb therapy. Approximately 30% of those who test positive for COVID-19 are eligible for the mAb treatment.
  - It is important to note that eligibility recommendations should focus on the severity of the risk factors that could contribute to rapid deterioration, not necessarily the severity of current COVID symptoms.
  - 65% of those who have received the treatment reported feeling better within two days, and less than 5% needed hospitalization after treatment. Less than 6% have mild and self-limiting complications from the infusion.
  - With the use of mAb therapy, there was found to be a 70% or greater decrease in hospital admissions or deaths per two randomized controlled trials of more than 5,000 patients.
  - Providers who wish to access these therapies in the course of treatment for high-risk patients with mild to moderate COVID-19, and for post-exposure prophylaxis in high-risk populations, may do so under the existing EUA.
- Health care organizations can order mAb directly from Amerisource Bergen Corporation. There is no shortage of supply. Therapies remain free of charge for requesting sites. Infusion administration charges are reimbursable through Medicare, Medicaid, and most third-party insurers. Review the direct ordering process guide.
  - In addition to infusion centers and hospitals, urgent care centers, surgical centers, dialysis centers, primary care practices, FQHCs, home care, LTCFs can also consider operationalizing to offer mAb therapy.
- Providers who need assistance locating an infusion site can call the mAb therapy call center at 1-877-366-0310 or visit Michigan.gov/COVIDTherapy.

MDHHS
Michigan Department of Health & Human Services

Providers or patients in need of assistance locating an infusion site, call the national Monoclonal Antibody Therapy Call Center, English 877-332-6585, Spanish 1-877-366-0310.

Visit Michigan.gov/COVIDtherapy for more information.