



# Monoclonal Antibody Therapy

## If a resident at a Skilled Nursing Facility has COVID-19, monoclonal antibody therapy may be the right option for both treatment and prophylaxis.

When administered to non-hospitalized, high-risk individuals as soon as possible after a positive test for COVID-19 and within 10 days of symptom onset, monoclonal antibody therapy improves symptoms and reduces the risk of hospitalizations and death. Monoclonal antibody therapy is also authorized for post-exposure prophylaxis of qualifying residents and staff with known exposure at Skilled Nursing Facilities.

Health care provider referrals are required for treatment and post-exposure prophylaxis. Talk to your staff and residents about the best treatment and prevention 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 take as little as 20 minutes or subcutaneous injection. This therapy is different than convalescent plasma collected from donors.

## Who can receive Monoclonal Antibody Therapy under the EUA?

Monoclonal antibodies are used for treatment or prevention, residents and staff must be at high risk for developing severe disease. Skilled Nursing Facility residents are likely to have one of the following risk factors:

- 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](#))
- 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 place individuals 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 [Certain Medical Conditions and Risk for Severe COVID-19 Illness](#).

**For treatment:** To receive monoclonal antibody therapy to treat COVID-19, high-risk individuals must:

- Test positive for COVID-19 (antigen or PCR).
- Be within 10 days of symptom onset.
- Not require hospitalization for COVID-19.
- Not require supplemental oxygen for COVID-19 beyond any non-COVID-19 oxygen therapy received.

**For post-exposure prophylaxis:** Monoclonal antibody therapies have received authorization for use as post-exposure prophylaxis 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 vaccination, 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 infection in other individuals in the same institutional setting.

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

## Planning Considerations

- 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 Emergency Use Authorization.
  - 95% of patients treated in Michigan reported no infusion related adverse events.
  - Studies done in over 5000 high-risk COVID-19 patients have reported a 70% reduction in hospitalizations and deaths compared to those treated with a placebo.
- The FDA has authorized the use of COVID-19 monoclonal antibody therapeutic REGEN-COV (casirivimab + imdevimab) and Eli Lilly's bamlanivimab + etesevimab for post-exposure prophylaxis (prevention) in select high-risk populations.
- Clinical staff should assess patients to identify individuals (e.g., close contacts) who might benefit from post-exposure prophylaxis.
  - Residents and staff of Skilled Nursing Facilities with high-risk conditions who are unvaccinated may be eligible for post-exposure prophylaxis, as well as those who are vaccinated but not expected to mount an adequate immune response (e.g., immunocompromised).
- MDHHS recommends mAb therapy be considered for COVID positive residents of Skilled Nursing Facilities. Most residents of Skilled Nursing Facilities meet high-risk criteria for treatment, which includes age, obesity, diabetes, heart and lung disease, and immunocompromising conditions.
  - Monoclonal antibody treatment is recommended regardless of immunization status. All monoclonal antibody therapy requires a physician's order and patient and/or guardian consent as outlined in the current Emergency Use Authorization.
  - Treatment should be started as soon as possible after receiving a positive COVID-19 test result, and within 10 days of symptom onset.
  - A single 20-minute intravenous (IV) infusion is recommended for treating COVID-19; however, subcutaneous injections of REGEN-COV may be given when intravenous access is not feasible (e.g., large outbreaks).
  - Patients must be observed for at least 60 minutes after intravenous infusion or subcutaneous injection.
  - Monoclonal antibody infusions do not require IV pumps and can be prepared at Skilled Nursing Facilities by nurses and paramedics.
  - Skilled Nursing Facilities should consider using on-site clinical personnel to administer monoclonal antibody therapy, whether via IV infusion or subcutaneous injection.
  - Facilities lacking resources to deliver medications can consult with the [Regional Healthcare Coalitions](#).
- Monoclonal antibody therapy medication is available at no cost to facilities through the federal government.
  - Monoclonal antibody medications are available at many specialty pharmacies throughout Michigan.
  - Infusion administration charges are reimbursable through Medicare, Medicaid, and most third-party insurers.
- **All Skilled Nursing Facilities should have a plan for using monoclonal antibodies for treatment and prevention before an outbreak occurs. For additional information, please contact MDHHS at [mdhhs-covid-therapies@michigan.gov](mailto:mdhhs-covid-therapies@michigan.gov).**