

Monoclonal Antibody Treatment for Children and Adults 4.28.2021 0800

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Over the last two weeks, daily pediatric cases of COVID 19 are 40% higher than during the peak of the fall 2020 surge. Children and young adults ages 10 to 20 have had the highest positivity rate: 20-28%. Although most pediatric cases of COVID-19 are mild or asymptomatic, severely ill patients have needed care in the SHWM pediatric ICU for the first time during this pandemic.

Promote this COVID-19 treatment

Help us encourage patients and families to consider the use of [monoclonal antibody treatment](#) for pediatric and adult patients who meet the eligibility criteria. This therapy is most effective if given as early as possible, preferably during the first 5 days from symptom onset and not later than 10. Patients can self-refer to our clinic by contacting the SHWM MAB at 616.391.0351.

MAB can help prevent hospitalization and death

Why is this so important? With MAB infusions, our goal to prevent progression of COVID-19 to severe disease, hospitalization and death. We have seen positive results with patients who receive MAB treatment and want to continue to promote this treatment and the recovery benefits it can bring.

Pediatric MAB is administered at Spectrum Health Blodgett Hospital with monitoring for infusion-related reactions, emergency response to serious reactions and after-care. The MAB clinic has infused over 600 patients to date. Overall, the infusion has been well tolerated. Adverse events are rare and usually mild. The majority of treated patients report feeling better starting 48 hours after the infusion.

Per [data released by Regeneron](#), MAB therapy reduces the hospitalization and death by 70%. From over 600 patients treated in our clinics, 23 were hospitalized, and there are no reported COVID-related deaths in those treated.

Details on Regeneron and eligibility criteria

The MAB infusion currently being used at Spectrum Health Blodgett Hospital is [Regeneron's casirivimab and imdevimab](#) combination, which also is being used at Spectrum Health Lakeland to treat COVID-19 patients as part of their COVID-19 Medication Therapies program. The authorization for Eli Lilly's bamlanivimab has been revoked due to poor efficacy against the novel variants that are currently dominant in Michigan.

Eligibility criteria for patients ages 12 through 17

Patients must meet ALL 6 criteria:

- Positive COVID-19 test
- Weigh at least 40 kg (or 88 pounds)
- Symptomatic; have any [COVID-19 related symptom](#)
- Duration of symptoms less than 10 days and patient is NOT hospitalized
- Not treated with convalescent plasma
- High risk of disease progression and at least 1 of the following risk factors for disease progression:
 - Congenital or acquired heart disease (unrepaired cyanotic heart disease, single ventricle physiology)
 - Chronic ventilator dependence
 - Asthma or chronic lung disease (including cystic fibrosis) with daily corticosteroid medication use for control

- BMI \geq 95th percentile, including patients with non-alcoholic fatty liver disease
- Diabetes (A1c \geq 13% or higher OR admission for DKA within 6 months)
- CKD including requiring dialysis
- Sickle Cell Disease (with history of acute chest syndrome)
- Severe Neurodevelopmental disorders (with dysphagia, airway clearance issues, or non-invasive ventilation requirements)
- Medical-related technology dependence (excluding sole gastrostomy tube)
- High-Level immune suppression
 - Within 2 months after HSCT OR HSCT recipients with prolonged high-level of immune suppression
 - 2 months after SOT or treatment within the last month for acute rejection
 - Leukemia not in remission
 - Within 4 months of CAR-T treatment
 - Molecularly defined immunodysregulatory disease
 - On immunosuppressive therapy
 - Prednisone \geq 20mg/day for at least 14 days (or the equivalent of prednisone, dexamethasone, solumedrol, methylprednisone, and deflazacort, see UpToDate comparison chart)
 - Corticotropin (ACTH)
 - Basiliximab (Simulect)
 - Abatacept (Orencia)
 - Antithymocyte globulin (Thymoglobulin)
 - Belatacept (Nulojix)
 - Methotrexate (Otrexup, Rasuvo, Rheumatrex, Trexall, Xatmep) \geq 0.4 mg/kg/week - case by case basis, in combination with other drugs.

Statements required by U.S. Food and Drug Administration

- Casirivimab and imdevimab treatment has not been approved but has been authorized for emergency use by FDA under an EUA, to treat mild to moderate COVID19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- The emergency use of casirivimab and imdevimab is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization revoked sooner.