High-Risk COVID-19 Outpatients May Avoid Hospitalization with Monoclonal Antibody Treatment

Is My Outpatient Eligible for Treatment?

Recent updates to the Emergency Use Authorizations for COVID-19 monoclonal antibodies by the FDA expanded the definition of "high-risk" outpatients who are eligible for treatment and provide greater latitude to healthcare providers to exercise their clinical judgment.

- Clinicians may now refer any adult or pediatric (age 12 years and older and ≥ 40kg) outpatient if they have a medical condition or other factor, including race/ethnicity, that puts them at higher risk for progressing to severe COVID-19.
- Eligibility is not limited to the medical conditions and factors listed below.
- For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Your outpatient may be eligible for monoclonal antibody treatment if they meet the following criteria[1]:

- Are an adult or pediatric (≥ 12 years of age and weighing at least 40 kg) patient
- Experienced the **onset in the last 10 days** of mild to moderate symptoms of COVID-19
- Have a positive test for COVID-19
- Are at high risk for progressing to severe COVID- 19 and/or hospitalization; high risk factors include but are not limited to:
  - Age ≥ 65 years of age
  - Obesity or being overweight based on CDC clinical growth charts [2]
  - Pregnancy
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease or immunosuppressive treatment
  - Cardiovascular disease or hypertension
  - Chronic lung diseases
  - Sickle cell disease
  - Neurodevelopmental disorders
  - Having a medical-related technological dependence (for example: tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID)

For more detail on the outpatient eligibility criteria for the authorized treatments, see the Fact Sheets on the FDA website.[1]

To guide outpatient treatment decisions, you should:

- Review the antiviral resistance information in Section 15 of the authorized fact sheets[1] for each monoclonal antibody therapy available under EUA for details on specific variants and resistance, and
- Refer to the CDC website, as well as information from state and local health authorities, for reports of viral variants in their region. [3]

In addition to outpatient treatments, on June 24, 2021, the FDA granted an EUA for a recombinant humanized monoclonal antibody (tocilizumab) for certain hospitalized COVID-19 patients.[4]

Early Action Is Vital

Early testing, identification, and referral are vital to access to outpatient monoclonal antibody treatment. So, consider:

- Discussing monoclonal antibodies, the importance of reporting symptoms, and COVID-19 testing with your high-risk patients during routine care appointments.
- Pre-identifying patients who may be eligible for monoclonal antibody treatment.

Local Infusion Locations

Tri-Hospital EMS:
Fax order and client information including client name, DOB, address, phone number, and a copy of client's positive COVID-19 result.
P: *810-989-4080 F: 810-985-5432*

Lake Huron Medical Center:
Fax order and call ER registration to confirm order has been sent. Hospital will contact patient to schedule appointment.
P: *810-216-1581 F: 810-216-1138*

McLaren Port Huron
Contact McLaren Port Huron's Outpatient Infusion Services to schedule treatment. Patients who are ill and in the hospital's Emergency Department can be scheduled for treatment as well.
P: 810-989-3283 (Press Option 2) F: 810-987-1532

ST. CLAIR COUNTY HEALTH DEPARTMENT
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References

1. Center for Drug Evaluation and Research (CDER) Fact Sheets For Health Care Providers Emergency Use Authorization (EUA) of REGEN-COVTM (casirivimab with imdevimab), Bamlanivimab and Etesevimab, and Sotrovimab.
https://www.fda.gov/media/145611/download
https://www.fda.gov/media/145802/download
https://www.fda.gov/media/149534/download

2. Centers for Disease Control and Prevention. Clinical Growth Charts.
https://www.cdc.gov/growthcharts/clinical_charts.htm

3. Centers for Disease Control and Prevention. Variant Proportions in the U.S.
http://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html

4 Center for Drug Evaluation and Research (CDER) Fact Sheets For Health Care Providers Emergency Use Authorization (EUA) for ACTEMRA® (tocilizumab).
https://www.fda.gov/media/150321/download