Is My Patient Eligible for Treatment?

On May 14, 2021, the FDA updated the Emergency Use Authorizations for COVID-19 monoclonal antibodies. These updates expand the definition of “high-risk” patients 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 ≥ 40 kg) patient 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 patient may be eligible for monoclonal antibody treatment if they meet the following criteria:

- 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
  - 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-19)

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

To guide treatment decisions, you should:

- Review the antiviral resistance information in Section 15 of the authorized fact sheets 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.
Early Action Is Vital

Early testing, identification, and referral are vital to access to 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

Your patient is not eligible for treatment if they:

- Are hospitalized due to COVID-19, OR
- Require oxygen therapy due to COVID-19, OR
- Require an increase in baseline oxygen flow rate due to COVID-19 for those on chronic oxygen therapy due to an underlying non-COVID-19 related comorbidity.

How to Find Infusion Locations

You can find infusion locations in your area:

- by visiting https://protect-public.hhs.gov/pages/therapeutics-distribution, OR
- by calling 1-877-332-6585 for English, or 1-877-366-0310 for Spanish

Contact the infusion location(s) to learn their referral procedures and whether they are accepting new patients.

For more information, visit CombatCOVID.hhs.gov


References

1. FACT SHEETS FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB AND ETSEVIMAB and CASIRIVIMAB AND IMDEVIMAB
   https://www.fda.gov/media/145802/download
   https://www.fda.gov/media/145611/download
2. CLINICAL GROWTH CHARTS. Centers for Disease Control and Prevention.
   https://www.cdc.gov/growthcharts/clinical_charts.htm
3. Variant Proportions in the U.S. Centers for Disease Control and Prevention.