High-Risk COVID-19 Positive and High-Risk COVID-19 Exposed 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 ≥ 40 kg) 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]:

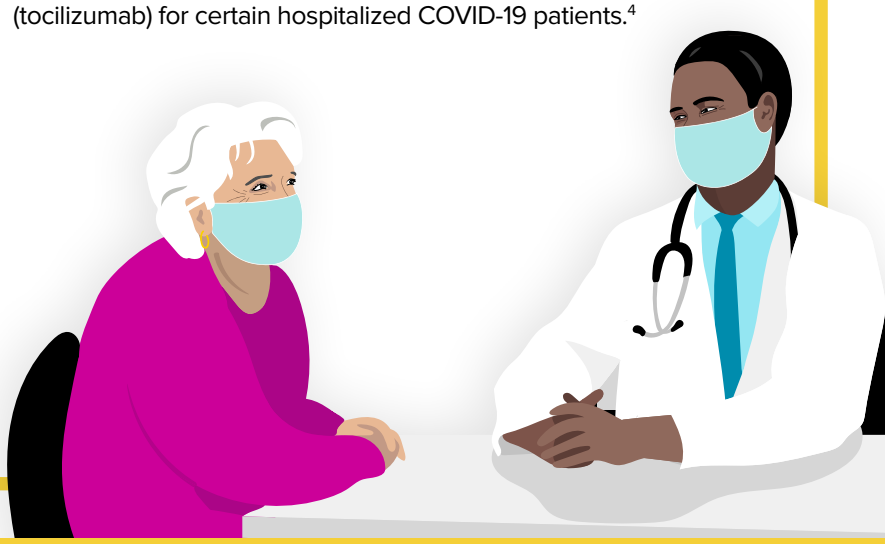
- Are an adult or pediatric (≥ 12 years of age and weighing at least 40 kg) patient
- Exposed to COVID-19 in the last 10 days
- Experienced the **onset in the last 10 days** of mild to moderate symptoms of COVID-19
- Have a positive test for COVID-19
- Are at high risk for progressing to severe COVID-19 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-19)

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.

How to Find Infusion Locations

You can find infusion locations in your area:

Scan this QR for Treatment locations

- 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.

The FDA also authorized subcutaneous injection for certain monoclonal antibody treatments that are currently available. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment.[1]

For more information, visit

CombatCOVID.hhs.gov

English: 1-877-332-6585 • Spanish: 1-877-366-0310

COMBATCOVID

https://nvhealthresponse.nv.gov/

References

1. Center for Drug Evaluation and Research (CDER) Fact Sheets For Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV™ (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