Monoclonal Antibody Therapy
FAQ for Clinicians

August 11, 2021

Indications for Treatment and Post-Exposure Prophylaxis

1. **Question:** Who is eligible to receive mAb therapy?

Answer: Anyone over 12 years of age weighing more than 40kg (89 pounds) and has one of the following high-risk factors making them more susceptible to severe COVID-19 illness:

- 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, Growth Charts - Clinical Growth Charts (cdc.gov))
- 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 also place individual patients 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 the CDC website: Certain Medical Conditions and Risk for Severe COVID-19 Illness | CDC

Casirivimab + imdevimab has also received authorization for use as post-exposure prophylaxis of COVID-19 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 complete vaccination (for example, indiviuals with immunocompromising conditions including those taking immunosuppressive medications) 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 COVID-19 infection in other individuals in the same institutional setting (for example, nursing home or correctional facility).

2. **Question:** Can patients admitted to a hospital for non-COVID reasons receive mAb therapy?

Answer: Yes. Per the applicable EUAs, these medications are not authorized for use in patients who are hospitalized due to COVID-19. mAb is permissible for other, non-COVID conditions (e.g., orthopedic, behavioral health, cardiac, etc.).

3. **Question:** Can patients receive mAb in observation status for COVID-19?

Answer: Per the FDA, observation status is not considered being "hospitalized" and patients may receive mAb for COVID provided they otherwise meet the qualifications (including no new or increased supplemental oxygen). The patient status may be changed to regular inpatient if the condition warrants.

4. **Question:** Can a patient receive mAb therapy if oxygen therapy was delivered prior to the infusion?

Answer: Yes. While mAb is not authorized in patients who require oxygen therapy for COVID-19 or who require an increase in baseline flow rate due to COVID-19. This oxygen requirement must not be present during the infusion. Before or after the infusion, oxygen therapy is permissible.

5. **Question:** May mAb therapy be prescribed "off-label" for patients who do not meet the eligibility requirements in the EUA but are considered to be at risk?

Answer: No. Because this medication is not approved by the FDA for any use, the prescribing clinician must strictly adhere to the EUA eligibility requirements.

6. **Question:** Are oral steroids considered an immunosuppressive therapy to qualify for mAb therapy?

Answer: Yes. Oral steroids are considered an immunosuppressive treatment regardless of the duration of therapy and would therefore meet mAb requirements.

7. **Question:** Can high-risk but asymptomatic patient who otherwise meets EUA requirements be eligible to receive mAb therapy?

Answer: To qualify for mAb treatment, a patient must have at least mild symptoms. These can include such things as loss of smell or taste, weakness, etc. However, post-exposure prophylaxis is now authorized for high-risk patients (see below).

Administering Monoclonal Antibodies

8. **Question:** How do my patients receive mAb therapy?

Answer: All monoclonal antibody therapies are administered through an intravenous (IV) infusion or, in limited cases, through subcutaneous injection. Antibodies may be administered only in settings where health care providers have immediate access to medications to treat any reactions and where emergency medical systems are available, if needed.

FOR TREATMENT, Intravenous infusion is strongly recommended. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment. FOR POST-EXPOSURE PROPHYLAXIS, either subcutaneous injection or intravenous infusion can be used.

9. **Question:** Is post exposure prophylaxis permitted?

Answer: Yes. Casirivimab + imdevimab has received authorization for use as post-exposure prophylaxis of COVID-19 in individuals who are at high risk of progression to severe COVID-19. See question 1 for full eligibility criteria. Of note, **pre-exposure** prophylaxis is not authorized.

10. **Question:** In determining eligibility for post-exposure prophylaxis, what are considered conditions that might result in an inadequate immune response to complete vaccination?

Answer: These include the following:

- People with immunosuppressive conditions
- People receiving immunosuppressive therapy
- People with hematologic cancers
- People on hemodialysis
- Other conditions (e.g., elderly)

11. **Question:** Is one on one nursing required for mAb therapy administration?

Answer: No. There is no requirement for patient to nurse/paramedic ratio. 4:1 is common in infusion clinics. Infusion pumps and/or cardiac monitors are not indicated.

12. **Question:** How often should vital signs be obtained during and after the infusion?

Answer: An initial and final (after observation) set of vital signs should always be obtained. When vital signs are normal, it is reasonable to repeat every 30 minutes. If vitals are, or become, abnormal, the frequency should be at least every 15 minutes until they return to normal.

13. **Question:** Can mAb be administered by the subcutaneous (SC) route?

Answer: Yes, The SC route is now authorized by the FDA for REGEN-Cov. For treatment, intravenous infusion is strongly recommended. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment. For post-exposure prophylaxis, either subcutaneous injection or intravenous infusion can be used.

14. **Question:** Should patients be premedicated with steroids, diphenhydramine, anti-emetics or other medications prior to beginning the mAb infusion?

Answer: There is no recommendation for any premedication prior to mAb infusions. Medications should be available for infusion related symptoms that might develop.

Operationalizing Monoclonal Antibodies

15. **Question:** Where do you store medicine?

Answer: Vials must be stored at refrigerated temperature (2°C–8°C / 36°F–46°F) until use. Monoclonal antibody therapies should not be frozen, shaken, or exposed to direct sunlight. Acceptable equipment for mAb storage also includes: 1) pharmacy grade refrigerator, 2) temperature monitoring system with back-up, and 3) alarm system for notification to authorized personnel of temperature deviations/excursions.

16. **Question:** Does the medication need to be prepared by a pharmacist or in a dedicated aseptic compounding area?

Answer: No. The medication may be prepared by any qualified healthcare professional (e.g., registered nurse, paramedic) using aseptic technique outside of a pharmacy. However, for administration inside of a hospital where pharmacy capabilities exist, the medication should be prepared in the hospital pharmacy.

17. **Question:** Can a primary care provider deliver mAb in their office?

Answer: Yes, provided they have qualified medical personnel to infuse and monitor the patient and an ability to respond to allergic reactions.

18. **Question:** Can mAb administered to multiple patients during an outbreak at a residential facility (e.g., long-term care)?

Answer: Yes. These types of outbreaks can be an important use for mAb therapy and post-exposure prophylaxis. Intravenous use for treatment can be provided on-site using internal staffing (e.g., nursing home nurses), home health nurses, paramedics, or a combination of these. Subcutaneous administration of REGEN-COV is authorized for treatment when intravenous administration is not feasible and would result in a delay in therapy. Post-exposure prophylaxis with REGEN-COV is authorized for qualifying high-risk patients by either the intravenous or subcutaneous routes.

19. **Question:** How can we increase the number of patients who receive monoclonal antibody treatment and post-exposure prophylaxis?

Answer: There are a number of important actions that can be taken by individual clinicians and heath care systems to expand access to this therapy.

Individual clinicians can alert high-risk patients who are being referred for testing that, if positive, they would qualify for monoclonal antibody therapy.

Clinicians should review all positive tests to identify eligible patients.

Patients who test positive but are not considered high-risk should be asked about potential need for post-exposure prophylaxis

Health care systems should adopt a proactive screening process of all patients who test positive to identify high-risk qualifying patients and potential opportunities for post-exposure prophylaxis among close contacts.

Local public health agencies should pursue monoclonal antibody treatment and post-exposure prophylaxis during outbreaks at residential facilities and other settings where clusters of cases occur.

20. **Question:** How do I become an eligible mAb provider?

Answer: Health care institutions have the ability to quickly order the monoclonal antibody therapies through direct ordering from AmerisourceBergen Corporation (ABC), the drugs sole distributer. There is no shortage in supply of these drugs, and the federal government has enough on hand to meet the needs of interested treatment facilities. The therapies remain free of charge to requesting sites.

- Review the direct ordering process guide
- Place an order with ABC

For facilities and health care providers interested in setting up infusions for high-risk patients with COVID-19, The Assistant Secretary for Preparedness and Response (ASPR) has many resources available. This includes free digital content that your facility can use on social media platforms to help educate providers and patients. Additionally, The U.S. Department of Health and Human Services has provided CombatCovid.HHS.gov as a resource for providers and patients.

Providers who need assistance locating an infusion site can call the mAb therapy call center at 1-877-366-0310 or visit Michigan.gov/COVIDTherapy.

MDHHS
Michigan Department of Health & Human Services