Nebraska Medicine
SERIOUS MEDICINE. EXTRAORDINARY CARE.®

Revision Date: 9/17/2021

COVID-19 Monoclonal Antibody (mAb) Therapy Process

There are now two indications for patients to receive COVID-19 mAb therapy; treatment for symptomatic infection and post-exposure prophylaxis (PEP). This guide describes the Nebraska Medicine process for patient evaluation of each situation.

Treatment Indication

Nebraska Medicine will screen all patients with a positive COVID-19 assay tested in-house for high-risk inclusion criteria to offer neutralizing antibody treatment as outlined below.

These high-risk criteria are some of those suggested under the FDA Emergency Use Authorization, and are the ones that will be automatically screened and potentially offered therapy:

- Age ≥65 years of age
- BMI ≥35 or BMI >85th percentile for age/gender based on CDC growth charts if age 12-17
- Diabetes
- Chronic Kidney Disease
- Immunosuppressed
- Cardiovascular disease
- Hypertension
- COPD/asthma, reactive airway or other chronic respiratory disease requiring drug therapy
- sickle cell disease
- congenital acquired heart disease
- neurodevelopmental disorders (ex. cerebral palsy)

This list is not all-inclusive of all high-risk criteria permitted under the EUA; please refer to the CDC website for an updated list. For patients that do not meet the criteria above for automated screening, please follow the detailed procedure below to contact the Pharmacy Outreach Team for patient inclusion.

As necessary due to limited appointment slots, patients may be prioritized based on date of symptom onset to ensure as many patients as possible are treated prior to the end of the duration set by the EUA (10 days for the treatment indication). If the patient elects to receive therapy, the medication will be ordered per protocol pursuant to policy.

Process for contacting the Pharmacy Outreach Team to request evaluation for manual inclusion, either due to not meeting the automated criteria or having a positive test outside of the Nebraska Medicine laboratory:

- If your patient has a positive PCR or antigen test for SARS-CoV-2:
  - Document note in One Chart reflecting your conversation with the patient, including the specific symptoms, symptom onset date, and inclusion criteria the patient meets which you judge to qualify them for mAb therapy
  - Scan test results into One Chart (or if not possible, attach result to e-mail below)
  - Email the monoclonal antibody pharmacist team at pharmacyoutreachteam@nebraskamed.com with the MRN of the patient for review
  - Pharmacy will review the documentation and call the patient to offer therapy within 24 hours, or will refer the case to Infectious Diseases for further review
- If your patient is symptomatic and appears to meet high-risk criteria but does not yet have a positive test result (or completed only a home test), please order SARS-CoV-2 testing through the Nebraska Medicine laboratory

Eligible patients will be contacted and educated on the risks/benefits/alternatives to receiving this therapy and this conversation will be documented in the medical record:

- If a patient does not answer the initial call a message will be left indicating that the call is time sensitive and must be returned within 24 hours to be eligible to receive the infusion
- If the call is not returned within this allocated timeframe, this will be documented in the medical record and the patient will be removed from the outreach call list

Infusions for the treatment indication are currently being performed at the Nebraska Medical Center only, due to infection control considerations and appropriate infusion site availability.

Nebraska Medicine
SERIOUS MEDICINE. EXTRAORDINARY CARE.®

Revision Date: 9/17/2021

Post-Exposure Prophylaxis (PEP) Indication

Patients who are at risk of severe COVID-19 and had a defined exposure may contact their providers to inquire about treatment in certain circumstances. Both casirivimab/imdevimab and bamlanivimab/etesevimab can now be utilized for prophylaxis in patients meeting the following criteria:

- Adults and pediatrics (12 years of age and older, weighing at least 40 kg) who are at high risk for progression to severe COVID-19, defined as:
    - Age ≥65 years of age
    - BMI ≥25 or BMI >85th percentile for age/gender based on CDC growth charts if age 12-17
    - Pregnancy
    - Diabetes
    - Chronic Kidney Disease
    - Immunosuppressed
    - Cardiovascular disease
    - Hypertension
    - COPD/asthma, reactive airway or other chronic respiratory disease requiring drug therapy
    - Sickle cell disease
    - Neurodevelopmental disorders or severe congenital anomalies
    - Medical-related technological dependence, not related to COVID-19

  This list is not all-inclusive of all high-risk criteria permitted under the EUA; please refer to the CDC website for an updated list. For patients that do not meet any of the defined criteria above, please include in a chart note the high-risk criteria for which you judge your patient to be eligible for therapy.

AND

- Those who are ***not fully vaccinated*** *or* ***who are not expected to mount an adequate immune response following a complete SARS-CoV-2 vaccination series*** (e.g., individuals with immunocompromising conditions, including those taking immunosuppressive medications)

AND

- Have been ***exposed to an individual infected with SARS-CoV-2*** consistent with CDC close contact criteria (within six feet of someone for a cumulative total of 15 minutes or more over a 24-hour period)
  OR
- Who are at ***high risk of exposure to an individual infected with SARS-CoV-2*** because of occurrence of COVID-19 infection in other individuals in the same institutional setting (e.g., nursing homes, prisons)

The EUA notes that this is not a substitute for vaccination against COVID-19 and does not extend to pre-exposure prophylaxis for prevention of COVID-19 (PrEP). The goal is to ideally administer mAb therapy for PEP as soon as possible and within 96hrs of exposure, although there is not a definitive maximum time on this as there is for the treatment indication. If the patient elects to receive therapy, the medication will be ordered per protocol pursuant to policy.

Qualified patients can be evaluated for mAb prophylaxis through one of the following methods:

- Document note in One Chart reflecting your conversation with the patient about mAb therapy, the high-risk inclusion criteria the patient meets which you judge to qualify them, their applicable vaccination status, and the details of the exposure or situation that meet the inclusion criteria above that qualify them for prophylaxis
- Email the monoclonal antibody pharmacist team at pharmacyoutreachteam@nebraskamed.com with the medical record number of the patient for review
- Pharmacy will review the documentation and call the patient to offer therapy within 24 hours, or will refer the case to Infectious Diseases for further review

Eligible patients will be contacted and educated on the risks/benefits/alternatives to receiving this therapy and this conversation will be documented in the medical record:

- If a patient does not answer the initial call a message will be left indicating that the call is time sensitive and must be returned within 24 hours to be eligible to receive the infusion
- If the call is not returned within this allocated timeframe, this will be documented in the medical record and the patient will be removed from the outreach call list

There is also a provision within the PEP indication for casirivimab/imdevimab that patients who have an ongoing exposure to SARS-CoV-2 that lasts longer than 4 weeks may receive subsequent scheduled doses of therapy every 4 weeks for the duration of ongoing exposure. For patients to be considered for ongoing PEP, please indicate this request specifically in your e-mail to the Pharmacy Outreach Team and provide additional detail on the nature of the ongoing exposure. You will then be contacted separately to discuss evaluation for patient eligibility for scheduled infusions.

Infusions for PEP are primarily being performed at Village Point Infusion Center.

General Information and Educational Resources

For patients or providers looking to identify local mAb infusion sites outside of Nebraska Medicine, please consult the interactive map at https://covid.infusioncenter.org/.

The below table has been created in order to help distinguish between the criteria and information needed for meeting criteria for either the treatment or post-exposure prophylaxis indications:

Characteristic / Requirement	Treatment Indication	Post-Exposure Prophylaxis
Positive SARS-CoV-2 Test	Yes (Antigen or PCR)	No
Meet high-risk criteria (EUA Language or CDC Detailed Guidance)	Yes	Yes
Maximum Timing from Symptom Onset / Exposure	10 days	None, but ASAP (within 96hrs used in studies)
Degree of Symptoms	Must have symptoms, but not progressed to hospitalization or oxygen therapy	None
Does vaccination status matter?	No	Must be unvaccinated, or vaccinated with an immunocompromising risk factor
Exposure Criteria	None	Meet CDC close contact criteria, or be at high-risk of exposure in an institutional setting (hospital, nursing home, prison, etc.)
Subcutaneous Route of Administration (cas/imdev product only!) (SubQ Administration Tip Sheet)	Yes, but only if IV not feasible or would lead to delay in treatment	Yes; OK as primary administration route

Additional patient-focused educational resources related to mAb therapy:

https://combatcovid.hhs.gov/i-have-covid-19-now/monoclonal-antibodies-high-risk-covid-19-positive-patients

https://combatcovid.hhs.gov/i-have-covid-19/how-do-i-know-if-im-high-risk
https://combatcovid.hhs.gov/i-have-covid-19-now/faqs-about-monoclonal-antibodies-consumers

Additional provider-focused educational resources related to mAb therapy:

https://combatcovid.hhs.gov/hcp/resources-clinicians
https://combatcovid.hhs.gov/sites/default/files/documents/E_Science-Behind-FAQs-062021.pdf

Authors:
Bryan Alexander, PharmD
Colleen Malashock, PharmD
Scott Bergman, PharmD
Trevor Van Schooneveld, MD