Nebraska Department of Health and Human Services

HEALTH ALERT NETWORK Update

NEBRASKA
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DEPT. OF HEALTH AND HUMAN SERVICES

TO: Healthcare Providers, Infection Control, Hospitals, Labs, and Public Health

FROM:

Matthew Donahue, MD	Bryan Alexander, PharmD	Gary Anthone, MD
Acting State Epidemiologist	Clinical Pharmacist	Director/CMO Public Health
Phone: 402-471-8566	Nebraska Medicine	Phone: 402-471-8566

RE: Updated COVID-19 Monoclonal Antibody (mAb) Therapy Indication & Change in Protocol for Ordering mAb Therapy

DATE: September 16, 2021

A new indication for COVID-19 monoclonal antibody (mAb) therapy has been granted emergency use authorization. In addition to the previous indication for treatment of symptomatic disease, casirivimab-imdevimab (REGEN-COV) can now be used for **post-exposure prophylaxis (PEP)**. A review of criteria for the new PEP indication and criteria for the existing treatment indication are outlined below. As of September 13th, 2021, the United States Government began allocating mAb therapy itself and accordingly, infusion sites will no longer be able to order mAb therapy directly from the distributor. When local supplies are limited and prioritization is necessary, using available doses for treatment is recommended over use for PEP in most situations.

With the current surge in COVID-19 in Nebraska, there is elevated need to use all tools at our disposal to prevent ongoing transmission, prevent hospitalizations, and reduce mortality. In addition to vaccination (our most effective intervention) and mitigation measures such as masking and distancing, mAb therapy should be considered preferentially whenever inclusion criteria are met. The official FDA provider fact sheet with detailed inclusion criteria is listed at https://www.fda.gov/media/145611/download.

Healthcare providers seeking mAb therapy for assisted living or skilled nursing facility patients, should complete a questionnaire at this link: https://redcap.nebraskamed.com/surveys/?s=74H88YD3RE. Staff from Nebraska's Infection Control Assessment and Promotion Program (ICAP) will respond within 24 hours to assist in arranging for infusion of mAb therapy. Healthcare providers seeking mAb therapy for patients not connected to such facilities should use the interactive map at https://covid.infusioncenter.org/ and engage their affiliated healthcare system or the nearest hospital. These parties can assist in arranging for infusion.

Post-exposure prophylaxis (PEP)

In addition to the use of mAb therapy for treatment of symptomatic disease, FDA has recently authorized use of casirivimab-imdevimab for PEP to *prevent* COVID-19 infection for individuals with a close contact exposure[1] OR for individuals who are at high risk for ongoing close contact exposure[1] (e.g., nursing facilities, prisons). For either indication, an individual is a candidate for PEP if:

- The individual is 12 years of age and older weighing at least 40kg *-AND-*
- The individual is high risk[2] for poor outcomes given age or medical history *-AND-*
- The individual is not fully-vaccinated or is not expected to mount an adequate response to vaccination (i.e., immunosuppressed)

For the PEP indication, mAb therapy should be administered as soon as possible after exposure (ideally within 96 hours). The subcutaneous route of administration is a co-primary route for this indication; subcutaneous administration does not have to be reserved for situations where intravenous administration is not feasible or immediately available. For individuals at high risk for ongoing close contact exposure, mAb therapy can be administered every four weeks (see provider fact sheet linked above for dosing).

Treatment of symptomatic disease
MAb therapy should continue being utilized for treatment of symptomatic disease if:

- The individual is 12 years of age and older weighing at least 40kg *-AND-*
- The individual is high risk[2] for poor outcomes given age or medical history *-AND-*
- The individual is within 10 days of symptom onset *-AND-*
- The individual has tested positive for SARS-CoV-2 *-AND-*
- The individual is not requiring supplemental oxygen (or more supplemental oxygen than baseline, if already using supplemental oxygen at baseline) or hospitalization for COVID-19 disease

For the treatment of symptomatic disease, intravenous administration is strongly preferred to subcutaneous administration, although subcutaneous administration is still an option when intravenous administration is not feasible or would lead to a delay in treatment.

[1]Close contact is defined here (https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html) as being within 6 feet of a person with COVID-19 for a total of 15 minutes or more over a 24 hour period, while that person is within their infectious period.

[2]High risk medical conditions for consideration are listed here (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html); please note this list is not exhaustive, and if a provider feels a patient's medical condition puts him or her at high risk for poor outcomes, that patient will still qualify for mAb therapy if the provider documents that assessment.

Patient-focused resources
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

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