Nebraska Department of Health and Human Services

# HEALTH ALERT NETWORK Update

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DEPT. OF HEALTH AND HUMAN SERVICES


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

FROM: Gary Anthone, MD
Director of Public Health and Chief Medical Officer
PHONE: 402-471-8566

Bryan Alexander, PharmD
Clinical Pharmacist
Nebraska Medicine


RE: COVID-19 Monoclonal Antibody (mAb) Therapy Updates & Sequencing

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COVID-19 monoclonal antibody (mAb) eligibility criteria are expanding, and providers should be aware that more high-risk conditions now qualify. DHHS, in collaboration with Nebraska Public Health Laboratory (NPHL) and Creighton University - CHI Health, has detected growing proportions of variants of concern (VOCs) with reduced susceptibility to bamlanivimab-etesevimab. All ordering and use of bamlanivimab-etesevimab should now be transitioned to casirivimab-imdevimab. A new mAb product sotrovimab is also expected to remain efficacious against VOCs with reduced susceptibility to bamlanivimab-etesevimab, and is expected to be available through routine pharmaceutical distributors in the coming weeks. Lastly, in addition to prior indications for sending specimens for sequencing, providers are requested to send nasopharyngeal specimens collected from all patients hospitalized with COVID-19 to NPHL (or to CHI Health Laboratory [Core Lab] if part of the CHI Health network).

**Updates and recommendations for use of COVID-19 monoclonal antibody (mAb) therapies**
Recently, the FDA expanded eligibility criteria that qualify patients to receive COVID-19 mAb therapy under the EUAs to include additional risk factors: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Each of these risk factors are applicable to all ages 12 and over, and this list is not exhaustive. Providers may now determine if a patient is high-risk even outside these defined criteria and recommend mAb therapy as long as their assessment criteria are documented. Although risk criteria are broadened, patients must still have a positive SARS-CoV-2 test, must not be hospitalized for COVID-19, and must be symptomatic (within 10 days of symptom onset) but not on supplemental oxygen. We continue to encourage use of these therapies for eligible patients in order to mitigate increased risk for hospitalization, morbidity, and mortality.

The proportion of SARS-CoV-2 VOCs with reduced susceptibility to bamlanivimab-etesevimab (P.1, B.1.351, and B.1.617) sequenced from Nebraska residents is growing. Accordingly, DHHS now recommends that all ordering and use of bamlanivimab-etesevimab mAb therapy be transitioned instead to casirivimab-imdevimab, for which activity against these VOCs remains robust. We are making this recommendation in advance of formal requirements for our state by FDA and CDC based on the projected expansion of these particular VOCs in the coming weeks in Nebraska. This step has already been taken by FDA and CDC in eight states (AZ, CA, FL, IL, IN, MA, OR, WA) where high proportions of these VOCs have been identified. As of last week, only 44% of all mAb infusions administered in Nebraska were casirivimab-imdevimab, and 29% of all institutional mAb infusion sites have yet to acquire casirivimab-imdevimab. We recommend stakeholders take action to ensure this therapy is available for supporting future needs in your community.

A number of important changes were made to casirivimab-imdevimab prescribing information on June 4th, 2021. The administered dose has been halved (600mg of each antibody), as recent studies have demonstrated equivalent efficacy with this lower dose. A subcutaneous route of administration has been added as an alternative to IV for patients where infusion is not feasible. Please review this new

information (https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf [regeneron.com]) and update site-specific protocols and informational materials accordingly.

A new mAb product sotrovimab has recently received an EUA for the same indications as the other two available products. This mAb is specifically targeted against a more highly conserved region of SARS-CoV-2 virus, and is expected to retain robust activity against VOCs including P.1, B.1.351, and B.1.617, as casirivimab-imdevimab does. Sotrovimab has similar clinical efficacy in reducing the risk of hospitalization to the other mAbs and is also prepared and administered as a single intravenous infusion of less than one hour. Sotrovimab is not going to be made available through the ASPR/DHHS ordering pathway from AmerisourceBergen; however, it can be procured through routine pharmaceutical distributors in the coming weeks at a currently unknown cost. Information available at: https://www.sotrovimab.com/hcp.

As previously, 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. For patients not connected to such facilities, providers should engage with their affiliated healthcare system or the nearest hospital. These parties can assist in arranging for infusion. For assistance in identifying locations in Nebraska capable of administering monoclonal antibodies, please go to: https://covid.infusioncenter.org.

**Request for sending specimens collected from patients hospitalized with COVID-19 for sequencing**
DHHS and partners are gaining better insight into SARS-CoV-2 VOC epidemiology in Nebraska because providers, laboratories, and local health departments across the state have collaborated in sending specimens for sequencing. No concerning trends between VOCs and vaccine breakthroughs, reinfections, or severe outcomes have emerged to date; however, identification of increasing proportions of SARS-CoV-2 VOCs with reduced susceptibility to bamlanivimab-etesevimab (P.1, B.1.351, and B.1.617) informed this recommendation to transition to casirivimab-imdevimab. Previously, we asked providers to send specimens to NPHL (or to CHI Health Laboratory [Core Lab] if part of the CHI Health network) under specific circumstances as follows:

- Potential reinfections
- Potential vaccine breakthroughs (i.e., COVID-19 infection ≥14 after a completed series)
- Patient presenting from areas or clusters experiencing rapid transmission, elevated attack rates, or elevated percent positivity
- Confirmatory testing of presumptive positive or presumptive negative results from SARS-CoV-2 antigen tests
- Returning travelers from out-of-state who have tested positive for SARS-CoV-2, or patients who have tested positive for SARS-CoV-2 and have been in contact with recently returned travelers

As COVID-19 case counts and hospitalizations decline throughout the state, the risk of new VOC introductions remains. We request providers *additionally* send nasopharyngeal specimens collected from all patients hospitalized with COVID-19 to NPHL (or to CHI Health Laboratory [Core Lab] if part of the CHI Health network). Obtaining genotypes from all patients hospitalized with COVID-19 will help facilitate earlier detection of a VOC possibly associated with more severe outcomes, if one emerges.

A HAN Advisory published on February 25th, 2021, entitled *Antigen Testing, Reinfections, Sequencing, & Antibody Test Reporting* described how to submit specimens to NPHL for sequencing. That HAN can be accessed at the following URL: https://dhhs.ne.gov/han%20Documents/UPDATE02252021.pdf. Please refer to "Instructions to order testing at NPHL for SARS-CoV-2 sequencing."