Nebraska Department of Health and Human Services

HEALTH ALERT NETWORK
Advisory

NEBRASKA
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DEPT. OF HEALTH AND HUMAN SERVICES

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

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RE: Monoclonal Antibodies for Treatment of COVID-19

DATE: December 24, 2020

On November 9 and November 21, FDA issued two Emergency Use Authorizations (EUA) for monoclonal antibodies to treat COVID-19. The indications and benefits of both of these therapies, bamlanivimab and the casirivimab/imdevimab, can be considered clinically equivalent. To date, over 1100 outpatients and 200 nursing home residents have received these therapies in Nebraska.

Both are indicated for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. Clinical trials suggest they reduce COVID-19-related hospitalization or emergency room visits within 28 days after treatment in patients at high risk for disease progression when compared to placebo.

The most important evidence that bamlanivimab may be effective came from the predefined secondary endpoint of reduced COVID-19-related hospitalizations or emergency room visits within 28 days after treatment. Among patients at high risk for disease progression, hospitalizations and emergency room visits occurred in 3% of bamlanivimab-treated patients compared to 10% in placebo-treated patients. The primary endpoint was change in viral load from baseline to Day 11 for bamlanivimab versus placebo. Most patients, including those receiving placebo, effectively cleared the virus by Day 11.

These monoclonal antibodies remain under investigation, both for inpatient and outpatient use. Therefore, they should not yet be seen as the standard-of-care for treatment of COVID-19 patients. However, due to their demonstrated safety in clinical trials to-date and their potential to mitigate COVID-19 related hospitalizations in Nebraska this winter, they are being encouraged for therapeutic consideration in appropriately selected patients. Available studies indicate that these therapies have a number-needed-to-treat of about 15 to prevent one ED visit or hospitalization.

Clinical requirements for use under the EUA (additional details available in references below):
- Authorized for patients with positive results of direct SARS-CoV-2 viral testing
- 12 years of age and older weighing at least 40 kilograms (about 88 pounds)
- Not indicated for asymptomatic patients nor for persons whose symptoms have progressed to the point where oxygen is required.
- At high risk for progressing to severe COVID-19 and/or hospitalization, including those 65 years of age or older, BMI ≥35, or who have certain chronic medical conditions.

• Administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary
• Administered as a single dose intravenously over 60 minutes

Recently, Nebraska has received weekly shipments of approximately 580 courses. Future allotments have not been specified. Last week approximately 83% of received courses were infused across the state. Currently, 62 geographically dispersed hospital pharmacies have received allocations. For hospitals or outpatient infusion centers interested in more information about participating as a site for infusion of these therapies, please contact: balexander@nebraskamed.com.

Health care providers seeking these therapies for assisted living, nursing home, or long-term care facility patients, should complete a survey 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 monoclonal antibody therapy. For patients outside of long term care/skilled nursing facilities, providers should engage with their affiliated health care system or network, or the nearest hospital. These parties can assist in arranging for infusion.

References:
FDA:
https://www.fda.gov/media/143605/download
https://www.fda.gov/media/143603/download

NIH COVID Treatment Guidelines, bamlanivimab:
https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-eua/
NIH COVID Treatment Guidelines, casirivimab/imdevimab:
https://www.covid19treatmentguidelines.nih.gov/statement-on-casirivimab-plus-imdevimab-eua/

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