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Distributed by the NH Health Alert Network <a href="mailto:DHHS.Health.Alert@dhhs.nh.gov">DHHS.Health.Alert@dhhs.nh.gov</a> February 15, 2022 Time 1400 (2:00 PM EDT) NH-HAN 20220215



## COVID-19 Pandemic, Update # 56 Bebtelovimab COVID-19 Monoclonal Antibody Therapy

## **Key Points and Recommendations:**

- On February 11<sup>th</sup>, the U.S. Food and Drug Administration (FDA) issued an <u>Emergency Use Authorization</u> (EUA) for Eli Lilly's bebtelovimab COVID-19 monoclonal antibody product.
  - Bebtelovimab is a recombinant neutralizing human IgG1k monoclonal antibody to the spike protein of the SARS-CoV-2 and is administered via an intravenous (IV) injection over at least 30 seconds ("IV push").
  - o Cell culture neutralization activity of bebtelovimab indicates that bebtelovimab retains effectiveness to the Omicron variants.
  - Providers administering this product should review and follow the instructions found in FDA's Fact Sheet for Healthcare Providers.
  - o Patients and caregivers need to be provided FDA's <u>Fact Sheet for Patients</u>, <u>Parents and Caregivers</u> prior to administration.
- The BLAZE-4 phase 1/2 clinical trial found that bebtelovimab recipients experienced a statistically significant reduction in viral load by day 5 after treatment compared to placebo and improvement of symptoms in patients with mild to moderate COVID-19.
- Providers should continue to refer to the <u>NIH COVID-19 Treatment Guidelines</u> and the <u>IDSA Guidelines</u> for treatment and prevention of COVID-19.
  - Review NIH's guidance on <u>use of monoclonal antibodies when Omicron is the predominant</u> circulating variant.
- The U.S. Department of Health and Human Services (HHS) distributes monoclonal antibody therapies through a state-coordinated allocation system; HHS will determine weekly distribution amounts for NH based on the weekly statewide incidence of new infections and hospitalizations, and product utilization.
- The NH Division of Public Health Services (NH DPHS) will then allocate treatments in the Health Partner Order Portal (HPOP) to NH administration facilities based on their requests and utilization, and the products will ship directly to the facility from AmerisourceBergen.
- To request bebtelovimab for administration, e-mail <a href="mailto:COVID19mAbDistribution@dhhs.nh.gov">COVID19mAbDistribution@dhhs.nh.gov</a>, or call 603-271-4463.
- Report any serious adverse events and medication errors upon administration to FDA's MedWatch.

- For any questions regarding this notification, please call the NH DHHS, DPHS, Bureau of Infectious Disease Control at (603) 271-4496 during business hours (8:00 a.m. 4:30 p.m.).
- If you are calling after hours or on the weekend, please call the New Hampshire Hospital switchboard at (603) 271-5300 and request the Public Health Professional on-call.
- To change your contact information in the NH Health Alert Network, please send an email to <a href="mailto:DHHS.Health.Alert@dhhs.nh.gov">DHHS.Health.Alert@dhhs.nh.gov</a>.

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