LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-08: FDA Authorizes New Monoclonal Antibody for Treatment for COVID-19 that Retains Activity Against Omicron Variant**
Origination Date: *February 17, 2022*	**Revision Dates (List All Revision Dates):**

FDA Authorizes New Monoclonal Antibody for Treatment of COVID-19 that Retains Activity Against Omicron Variant

The FDA has issued an Emergency Use Authorization (EUA) for Eli Lilly's bebtelovimab for the treatment of mild to moderate COVID-19 adults and pediatric patients who:

- Are 12 years of age and older weighing at least 40 kilograms (which is about 88 pounds),
- Have a positive COVID-19 test,
- Are at high risk for progression to severe COVID-19, including hospitalization or death, and
- Have no accessible or clinically appropriate alternative COVID-19 treatment options approved or authorized by the FDA.

Emergency Use Authorization is different than FDA approval. Based on the FDA's review of the scientific evidence available, the agency has determined that it is reasonable to believe that bebtelovimab may be effective in treating certain patients with mild or moderate COVID-19.

Bebtelovimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. Treatment with bebtelovimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bebtelovimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

Bebtelovimab works by binding to the spike protein of the virus that causes COVID-19, similar to other monoclonal antibodies that have been authorized for the treatment of high-risk patients with mild to moderate COVID-19 and shown a benefit in reducing the risk of hospitalization or death.

The FDA is carefully monitoring circulating viral variants and their sensitivity to authorized monoclonal antibodies, including bebtelovimab. Laboratory testing showed that bebtelovimab retains activity against both the omicron variant and the BA.2 omicron subvariant.

At this moment supply of bebtelovimab remains limited. A list of facilities in Louisiana receiving allocations of monoclonal antibodies, including bebtelovimab, can be found here https://ldh.la.gov/page/monoclonal-antibodies

Dosage: The dosage in adults (18 years and older) and pediatric patients (≥12 years of age and weighing at least 40 kg) is 175 mg administered as a single intravenous injection over at least 30 seconds

Fact sheets
Under the EUA, fact sheets that provide important information about using bebtelovimab for the treatment COVID-19 as authorized must be made available to patients and caregivers. These fact sheets include dosing instructions, potential side effects and drug interactions. Clinicians should closely review the FDA fact sheet for healthcare providers.

Fact sheet for healthcare providers: https://www.fda.gov/media/156152/download
Fact sheet for patients, parents, and caregivers: https://www.fda.gov/media/156153/download
Emergency Use Authorization documentation link: https://www.fda.gov/media/156151/download