Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
February 14, 2022

United States Food and Drug Administration (FDA) authorizes Eli Lilly's COVID-19 Monoclonal Antibody Drug Bebtelovimab

On February 11, 2022, the U.S. FDA granted emergency use authorization (EUA) to Eli Lilly's new monoclonal antibody drug bebtelovimab based on positive clinical trial data. Laboratory studies have confirmed that the drug retains activity against the Omicron variant of the coronavirus. With this authorization, health care providers now have four drugs that have proven effective against the Omicron variant (the monoclonal antibody sotrovimab/Xevudy and the oral antivirals nirmatrelvir and ritonavir/Paxlovid and molnupiravir).

It has been reported that the U.S. government has purchased 600,000 doses and that the Alabama Department of Public Health will begin ordering on February 14, 2022 for statewide distribution upon receipt. It is anticipated that this allocation will effectively double the state's allocation of monoclonal antibody products delivered weekly.

Like previous products, the EUA grants the emergency use of bebtelovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg). Patients must have positive results of direct SARS-CoV-2 viral testing (not antibody testing) and must be at high risk for progression to severe COVID-19, including hospitalization or death. Also, the authorization restricts use to patients for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

The dosage of bebtelovimab in adults (18 years and older) and pediatric patients (≥12 years of age and weighing at least 40 kg) is 175 mg. The drug must be administered as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 7 days of symptom onset. Bebtelovimab must be administered as a single intravenous injection over at least 30 seconds.

Patients receiving the treatment must be clinically observed for at least 1 hour after injection is complete for possible infusion-related reactions. Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of other SARS-CoV-2 monoclonal antibodies and could occur with administration of bebtelovimab.

Please see the following resources for more information:
https://www.fda.gov/media/156151/download

Fact Sheet for Patients, Parents, and Caregivers: http://pi.lilly.com/eua/bebtelovimab-eua-factsheet-patient.pdf

Fact Sheet for HealthCare Providers: http://pi.lilly.com/eua/bebtelovimab-eua-factsheet-hcp.pdf