TEXAS Health and Human Services | Texas Department of State Health Services

Bebtelovimab EUA

February 12, 2022

On February 11, 2022, bebtelovimab, an investigational monoclonal antibody treatment for COVID-19 received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). The indications for the bebtelovimab, developed by Eli Lilly and Company, are 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), and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

Studies using pseudovirus and authentic virus indicate that bebtelovimab is able to neutralize the Omicron variant of SARS-CoV-2, the virus that causes COVID-19.

- The authorized dose of bebtelovimab is 175 mg given as an **intravenous injection** over at least 30 seconds.
- Bebtelovimab should be administered as soon as possible after a positive viral (molecular or antigen) test for SARS-CoV-2 and within **seven** (7) days of symptom onset.
- Bebtelovimab is not authorized for use in patients who:
    - are hospitalized due to COVID-19, OR
    - require oxygen therapy and/or respiratory support due to COVID19, OR
    - require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID19 related comorbidity.
- Each facility must have the capability to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS).
- Administered doses must be reported via ImmTrac2.
- Additional federal reporting will be required. Details will be shared as available.
- The product will be provided free of cost, and facilities will be able to charge an administration fee. Coding and billing information will be posted to CMS when it is available.

US HHS has purchased bebtelovimab for distribution to providers via state and territorial health departments. DSHS will allocate bebtelovimab in a similar manner as previous allocations of other monoclonal antibodies used to treat COVID-19 patients – based on disease burden and geographical distribution. Details on how to order bebtelovimab will be made available in the coming days.

Resources

FACT SHEET FOR HEALTHCARE PROVIDERS

FACT SHEET FOR PATIENTS, PARENTS, and CAREGIVERS

Frequently Asked Questions on the Emergency Use Authorization of Bebtelovimab