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FDA grants EUA to outpatient COVID-19 treatment for children, adults

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For the latest news on COVID-19, visithttps://www.aappublications.org/news/2020/01/28/coronavirus.

The Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for an investigational COVID-19 treatment that can be used in patients as young as 12 years.

Eli Lilly and Company's monoclonal antibody therapy bamlanivimab is intended to treat mild to moderate COVID-19 in outpatient settings and has been shown to reduce hospitalization and emergency department (ED) visits.

"The FDA's emergency authorization of bamlanivimab provides health care professionals on the frontline of this pandemic with another potential tool in treating COVID-19 patients," Patrizia Cavazzoni, M.D., acting director of the FDA's Center for Drug Evaluation and Research, said in a news release. "We will continue to evaluate new data on the safety and efficacy of bamlanivimab as they become available."

Monoclonal antibodies mimic the immune system's ability to fight off viruses, according to the FDA. Bamlanivimab is designed to block the SARS-CoV-2 virus' attachment and entry into human cells.

The treatment was tested in a randomized, double-blind, placebo-controlled clinical trial in 465 non-hospitalized adults with mild to moderate COVID-19 symptoms. About 3% of those treated with

bamlanivimab later required hospitalization or an ED visit compared to 10% of patients treated with a placebo.

Bamlanivimab is authorized for patients who are at least 12 years old and weigh at least 40 kilograms and who are at high risk for progressing to severe COVID-19. It should not be used in patients who are hospitalized or require oxygen therapy.

Patients are considered high risk if they have a body mass index (BMI) of 35 or higher, chronic kidney disease, diabetes, immunosuppressive disease, are receiving immunosuppressive treatments or are at least 65 years of age. Children ages 12-17 also are considered high risk if they have a BMI at or above the 85th percentile, sickle cell disease, congenital or acquired heart disease, neurodevelopmental disorders, a medical-related technological dependence, asthma or other chronic respiratory disease that requires daily medication for control.

Bamlanivimab should be given as soon as possible after testing positive for SARS-CoV-2 and within 10 days of symptom onset. It is administered via intravenous infusion. Possible side effects include anaphylaxis and infusion-related reactions, nausea, diarrhea, dizziness, headache, itching and vomiting.

The U.S. government has purchased 300,000 doses for 2020 and could purchase up to 650,000 more next year. They will be distributed to states based on their COVID-19 case counts. States will allocate the doses to health care facilities.

Resources

- Bamlanivimab fact sheet for health care providers
- Bamlanivimab fact sheet for patients and caregivers
- Information from the Centers for Disease Control and Prevention about COVID-19 for health care professionals
- Information about COVID-19 from the AAP Red Book
- Information about COVID-19 from the AAP
- Information for parents from HealthyChildren.org on coronavirus