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FDA expands EUA for monoclonal antibodies to include young children

December 3, 2021

Article type: News
Topics: COVID-19, Infectious Diseases, Pharmacology

Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

A combination of two monoclonal antibodies has been authorized to prevent and treat COVID-19 in young children.

The Food and Drug Administration (FDA) announced Friday it has expanded emergency use authorization (EUA) for bamlanivimab and etesevimab in children under 12 years.

The investigational medicines from Eli Lilly and Co. must be administered together via intravenous infusion. They can be used for children of all ages at high risk for severe COVID-19 as post-exposure prophylaxis to prevent COVID or as treatment for those who have contracted SARS-CoV-2. The monoclonal antibodies previously were authorized for people 12 years and older.

"Children under one year of age who are exposed to the virus that causes COVID-19 may be at particularly high risk for severe COVID-19 and this authorization addresses the medical needs of this vulnerable population," FDA Center for Drug Evaluation and Research Director Patrizia Cavazzoni, M.D., said in a press release. "While today's authorization includes post-exposure prevention of COVID-19 in children, this therapeutic option is not a substitute for vaccination. Vaccines remain our best tool in the fight against the virus and there is a COVID-19 vaccine authorized for children 5 years of age and above."

Conditions that may put children at increased risk for severe disease include obesity or overweight, chronic kidney disease, diabetes, immunosuppressive disease/treatment, cardiovascular disease, chronic lung

diseases, sickle cell disease, neurodevelopmental disorders and having a medically related technological dependence.

Bamlanivimab and etesevimab block the SARS-CoV-2 virus' attachment and entry into human cells, according to the FDA. The monoclonal antibodies were studied in a clinical trial that included 125 children at risk for severe COVID-19. Hypersensitivity, anaphylaxis and infusion-related reactions have been reported after use. Possible side effects include nausea, dizziness, itchy skin and rash.

Resources

- Fact sheet for health care providers
- Fact sheet for patients, parents and caregivers
- Frequently asked questions on the emergency use authorization for bamlanivimab and etesevimab