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AAP answers questions on monoclonal antibody therapy use in children, adolescents

by Trisha Korioth, Staff Writer

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

An AAP FAQ outlines the Food and Drug Administration (FDA) emergency use criteria for outpatient treatment with SARS-CoV-2 monoclonal antibody therapy in eligible children.

The FAQ describes two sets of criteria for monoclonal antibody therapy use in high-risk individuals 12 years and older who have certain host factors and underlying medical conditions in outpatient settings: 1) treatment of mild or moderate acute COVID-19 and 2) COVID-19 post-exposure prophylaxis.

Monoclonal antibody therapies that have received FDA emergency use authorization (EUA) for outpatient treatment include casirivimab and imdevimab administered together; bamlanivimab and etesevimab administered together; and sotrovimab.

Patients with any of the high-risk conditions who meet the FDA EUA criteria can receive monoclonal antibody therapy. Patients must be 12 years or older and weigh at least 40 kilograms.

Data on efficacy and safety of investigational therapies in children are "limited and emerging," according to the AAP. No *controlled* studies demonstrate which children or adolescents would benefit most from monoclonal antibody therapy.

The FAQ describes which patients are considered high risk. It outlines the high-risk criteria conditions that are associated with severe COVID-19 in children and adolescents have been described in *non-controlled* studies. These include:

- body mass index at the 85th percentile or higher;
- immunosuppressive disease or receipt of immunosuppressive therapies; or
- medical-related technological dependence (i.e., tracheostomy, positive pressure ventilation) that is not

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related to COVID-19.

High-risk criteria conditions also include neurodevelopmental disorders, sickle cell disease, congenital or acquired heart disease, asthma or reactive airway or other chronic respiratory disease that requires daily medication for control, diabetes, chronic kidney disease or pregnancy.

Pediatricians can find information in the FAQ on initiation/timing of monoclonal antibody therapy administration, precautions to take when administering monoclonal antibodies, coding, and information about self-isolation, quarantine, COVID-19 vaccination and preventive measures.

Resources

- Infectious Diseases Society of America guidelines on treatment of patients with COVID19, https://bit.ly/2Vlwzz8
- Information from the AAP Red Book on SARS-CoV-2, https://bit.ly/38Kl1Zk