



FDA approves COVID-19 treatment for children under 12

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

The Food and Drug Administration (FDA) has approved the use of Veklury (remdesivir) to treat COVID-19 in certain infants and children under 12 years.

The treatment from Gilead Sciences Inc. can be used for children 28 days and older weighing at least 3 kilograms who are hospitalized with COVID-19 as well as non-hospitalized children who are at risk for severe COVID-19.

“As COVID-19 can cause severe illness in children, some of whom do not currently have a vaccination option, there continues to be a need for safe and effective COVID-19 treatment options for this population,” Patrizia Cavazzoni, M.D., director of the FDA’s Center for Drug Evaluation and Research, said in a [press release](#).

The treatment, which is given by injection, prevents the SARS-CoV-2 virus from replicating. It previously was approved for people 12 years and older weighing at least 40 kilograms but also could be used under emergency use authorization for younger children.

Full approval in children is based on phase 3 clinical trial data in adults as well as a phase 2/3 [clinical study](#) of about 50 children and adolescents who received Veklury for up to 10 days. Possible side effects include increased liver enzyme levels and allergic reactions.

The Centers for Disease Control and Prevention (CDC) [issued a health advisory](#) Monday advising against the use of unproven COVID-19 treatments. Systemic corticosteroids should not be used for patients with

mild to moderate COVID-19 who do not require supplemental oxygen. The CDC also does not recommend antibacterial therapy in the absence of another indication.

“... these drugs can cause harm and provide no demonstrated benefit in patients with COVID-19 with no supplemental oxygen requirement or bacterial coinfection,” according to the health advisory.

The AAP and federal health officials continue to urge everyone who is eligible to get vaccinated.

Resources

- [National Institutes of Health COVID-19 treatment guidelines](#)
- [AAP interim guidance on outpatient management of COVID-19](#)
- [Information from the CDC on COVID-19 treatments](#)

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