

ADMINISTRATION

FDA grants full approval for COVID-19 treatment remdesivir in young kids

BY PETER SULLIVAN - 04/25/22 3:45 PM ET

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The Food and Drug Administration (FDA) on Monday gave its first full approval for a COVID-19 treatment for children under 12.

The agency granted approval to the treatment remdesivir, also known as Veklury, made by Gilead Sciences, which has already been approved as a treatment for adults.

Still, the FDA stressed that remdesivir is not a replacement for vaccination, and there is still no authorized vaccine for children under 5, a source of stress and disappointment for some parents.

Rep. [James Clyburn](#) (D-S.C.), the chair of the House Select Subcommittee on the Coronavirus Crisis, earlier on Monday requested an FDA briefing on the agency's progress on authorizing a vaccine for children under five.

Authorization for the Pfizer vaccine for young kids could come in June, though previous timelines have been pushed back before.

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While the virus is generally less dangerous in children, the FDA noted severe illness can still result.

"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," said Patrizia Cavazzoni, director of the FDA's Center for Drug Evaluation and Research. "Today's approval of the first COVID-19 therapeutic for this population demonstrates the agency's commitment to that need."

The approval covers children 28 days and older who weigh at least 3 kilograms and are either hospitalized or at high-risk of severe illness.

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