FDA approves first COVID treatment for use in kids

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The U.S. Food and Drug Administration on Tuesday approved the

antiviral remdesivir as the first COVID-19 treatment for young children.

The drug had so far only been available to this age group under a special FDA emergency use authorization order.

Now, doctors treating kids under 12 who are hospitalized or are at home with mild-to-moderate COVID but a high risk for severe COVID can readily prescribe Veklury (remdesivir) to their young patients. Remdesivir had already been fully approved to treat people 12 and older.

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

In a news release from drug maker Gilead Sciences, one pediatric infectious diseases doctor welcomed the news.

"This approval means that remdesivir can potentially provide meaningful clinical improvement, by reducing disease progression and helping children recover from COVID-19 more quickly," said Dr. Amina Ahmed, from Atrium Health-Levine Children's Hospital in Charlotte, N.C. "We need proven antiviral treatment options, like remdesivir, that can help treat some of the most vulnerable in our society: children."

The FDA noted that Veklury is not a substitute for getting a vaccination, although there is not yet a vaccine approved for children aged 4 and younger. Two COVID vaccines, Pfizer and Moderna, have been fully approved and three are available for emergency use, depending on age. The vaccines are meant to prevent serious clinical outcomes, including

hospitalization and death, the FDA said. People should also receive a booster, if eligible, the agency added.

The approval was based on results from a phase 3 clinical trial for adults, the FDA said, noting that the course of the disease is similar in both adult and pediatric patients.

It is also supported by a phase 2/3 clinical study of 53 pediatric patients, the FDA said. Patients in that study had a confirmed COVID infection ranging from mild to severe and received the medication for 10 days. Results, including safety results, were similar to those already seen in adults, the agency said.

Possible side effects of the drug, which can only be delivered via injection, include increased levels of liver enzymes, which may be a sign of liver injury; and allergic reactions, which may include changes in blood pressure and heart rate, low blood oxygen level, fever, shortness of breath, wheezing, swelling, rash, nausea, sweating or shivering.

More information: The U.S. Centers for Disease Control and Prevention has more on COVID-19.