

FDA approves first treatment for COVID-19

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December 2020—The FDA approved Gilead Sciences' antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should be administered only in a hospital or health care setting capable of providing acute care comparable to inpatient hospital care. Veklury is the first treatment for COVID-19 to receive FDA approval.

The approval does not include the entire population that had been authorized to use Veklury under an emergency use authorization originally issued on May 1. The FDA revised the EUA for Veklury to authorize the drug's use for treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. Clinical trials assessing the safety and efficacy of Veklury in this pediatric patient population are ongoing.

The approval of Veklury was supported by the agency's analysis of data from three randomized, controlled clinical trials that included patients hospitalized with mild to severe COVID-19.

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