

## Veklury® (remdesivir) – Revised emergency use authorization

- On January 21, 2022, the [FDA revised the emergency use authorization \(EUA\)](#) for Gilead's [Veklury \(remdesivir\)](#), for the treatment of pediatric patients weighing 3.5 kilograms to less than 40 kilograms or pediatric patients less than 12 years of age weighing at least 3.5 kilograms, with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are *not hospitalized* and have mild-to-moderate coronavirus disease 2019 (COVID-19), and are at high risk for progression to severe COVID-19, including hospitalization or death.
  - Previously, the EUA allowed for treatment of this same group of patients who were hospitalized.
- Veklury is FDA-approved for the treatment of COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, who are hospitalized; or not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.
  - Adults and pediatric patients (12 years of age and older and weighing at least 40 kg) who are *not hospitalized* expanded indication was approved on January 21, 2022.
- Given the similar course of COVID-19 disease, the authorization of Veklury in certain pediatric patients is based on extrapolation of efficacy from adequate and well-controlled studies in adults.
- The recommended dose of Veklury for the treatment of non-hospitalized pediatric patients weighing 3.5 kilograms to less than 40 kilograms or pediatric patients less than 12 years of age weighing at least 3.5 kilograms is an intravenous infusion for 3 days as follows:

Body weight	Loading dose (Day 1)	Maintenance dose (Day 2 and 3)
3.5 kg to less than 40 kg	5 mg/kg	2.5 mg/kg
40 kg and higher	200 mg	100 mg

- The treatment course of Veklury should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made and within 7 days of symptom onset.
- Refer to the Veklury EUA for dosing recommendations for hospitalized pediatric patients weighing 3.5 kilograms to less than 40 kilograms or pediatric patients less than 12 years of age weighing at least 3.5 kilograms.
- Refer to the Veklury drug label for dosing recommendations for hospitalized and non-hospitalized adult and pediatric patients (12 years of age and older and weighing at least 40 kg).