

Veklury[®] (remdesivir) – Expanded indication

- On January 20, 2022, the FDA approved Gilead's [Veklury \(remdesivir\)](#), for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.
 - Previously, Veklury was approved for the same indication in hospitalized patients only.
- The approval of Veklury for the expanded indication was based on a randomized, double-blind, placebo-controlled study in 554 adults and 8 pediatric patients who were unvaccinated, non-hospitalized, had mild-to-moderate COVID-19, were symptomatic for COVID-19 for ≤ 7 days, had confirmed SARS-CoV-2 infection, and had at least one risk factor for progression to hospitalization. Patients received 3 days of standard of care + Veklury or placebo. The primary endpoint was the proportion of patients with COVID-19 related hospitalization (defined as at least 24 hours of acute care) or all-cause mortality through day 28.
 - Events occurred in 2 (0.7%) patients treated with Veklury vs. 15 (5.3%) patients with placebo (hazard ratio 0.134, 95% CI: 0.031, 0.586; p = 0.0076). No deaths were observed through day 28.
- The recommended dose of Veklury for the treatment of non-hospitalized adults and pediatric patients 12 years of age and older and weighing at least 40 kg is a single loading dose of 200 mg on day 1 via intravenous (IV) infusion followed by once-daily maintenance doses of 100 mg from day 2 via IV infusion for a total treatment duration of 3 days.
 - 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 drug label for dosing recommendations for hospitalized patients.