

## Veklury<sup>®</sup> (remdesivir) – Expanded indication

- On April 25, 2022, the [FDA approved Gilead's Veklury \(remdesivir\)](#), for the treatment of coronavirus disease 2019 (COVID-19) in pediatric patients ( $\geq 28$  days old and weighing  $\geq 3$  kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (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.
  - Previously, this indication was available under an emergency use authorization (EUA).
  - In addition, this indication is also approved for adults and adolescent patients ( $\geq 12$  years of age).
- The approval of Veklury for this indication was based on data from clinical studies in adults and an open-label study in 53 hospitalized pediatric patients with confirmed SARS-CoV-2 infection. Patients received Veklury for up to 10 days.
  - Treatment with Veklury resulted in an overall median change from baseline in clinical status of +2.0 points on day 10.
  - Recovery was reported for 62% of patients on day 10; median time to recovery was 7 days.
- The recommended dosage of Veklury for pediatric patients 28 days of age and older and weighing 3 kg to less than 40 kg is a single loading dose of 5 mg/kg on day 1 via intravenous (IV) infusion followed by once-daily maintenance doses of 2.5 mg/kg from day 2 via IV infusion.
  - The treatment course of Veklury should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made in hospitalized patients, and within 7 days of symptom onset in non-hospitalized patients.
  - The recommended total treatment duration for hospitalized patients requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO) is 10 days.
  - The recommended treatment duration for hospitalized patients not requiring invasive mechanical ventilation and/or ECMO is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days.
  - The recommended total treatment duration for non-hospitalized patients is 3 days.
  - Refer to the Veklury drug label for dosing recommendations for hospitalized and non-hospitalized adult and pediatric patients weighing at least 40 kg.