Veklury® (remdesivir) – Expanded indication

- On February 28, 2024, the FDA approved Gilead's Veklury (remdesivir), for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (birth to less than 18 years of age weighing at least 1.5 kg) who are: (1) hospitalized, or (2) not hospitalized and have mild-to-moderate COVID-19 and, are at high risk for progression to severe COVID-19, including hospitalization or death.
    - Veklury was previously approved for this indication in pediatric patients 28 days of age and older and weighing at least 3 kg.
- The use of Veklury in pediatric patients from birth to less than 18 years of age and weighing at least 1.5 kg is supported by Study 5823 where 58 hospitalized pediatric subjects were treated with weight-based Veklury for up to 10 days.
    - The safety and pharmacokinetic results in pediatric subjects were similar to those in adults.
- The recommended intravenous dose of Veklury in pediatric patients less than 28 days old and at least 1.5 kg is 2.5 mg/kg on day 1 and 1.25 mg/kg once daily from day 2. The treatment course should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made.
    - 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 diagnosed with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death, is 3 days.
    - The only approved dosage form of Veklury for pediatric patients weighing 1.5 kg to less than 40 kg is Veklury for injection (supplied as 100 mg lyophilized powder in vial).
- Refer to the Veklury drug label for dosing for other patient populations.