

Veklury® (remdesivir)

When requesting Veklury® (remdesivir), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (birth to less than 18 years of age and weighing at least 1.5 kg) who have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

Coverage Guidelines

Coronavirus Disease 2019 (COVID-19)

The individual must meet **all** of the following criteria for authorization:

- Weighs at least 1.5 kg;
- Has tested positive for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);
- Patient is at high risk of progression to severe COVID-19

Approval duration: 3 days (one treatment course)

Dosing Recommendations

The recommended dosage for adults and pediatric patients weighing at least 40 kg is a single loading dose of Veklury 200 mg on Day 1 via intravenous infusion followed by once-daily maintenance doses of 100 mg from Day 2 for a total treatment duration of 3 days.

The recommended dosage for pediatric patients 28 days of age and older and weighing 3 kg to less than 40 kg is a single loading dose of Veklury 5 mg/kg on Day 1 via intravenous infusion followed by once-daily maintenance doses of 2.5 mg/kg from Day 2 for a total treatment duration of 3 days.

The recommended dosage for pediatric patients 28 days of age and older and weighing 1.5 kg to less than 3 kg is a single loading dose of Veklury 2.5 mg/kg on Day 1 via intravenous infusion followed by once-daily maintenance doses of 1.25 mg/kg from Day 2 for a total treatment duration of 3 days.

The recommended dosage for pediatric patients younger than 28 days of age and weighing 1.5 kg or more is a single loading dose of Veklury 2.5 mg/kg on Day 1 via

intravenous infusion followed by once-daily maintenance doses of 1.25 mg/kg from Day 2 for a total treatment duration of 3 days.

References

1. Veklury intravenous infusion [prescribing information]. Foster City, CA: Gilead; February 2024.
2. COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. February 29, 2024. Available at: <https://www.covid19treatmentguidelines.nih.gov/>. Accessed on April 29, 2024.
3. Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Disease Society of America Guidelines on the treatment and management of patients with COVID-19. June 26, 2023. Available at: <https://www.idsociety.org/COVID19guidelines>. Accessed April 29, 2024.
4. Data on file. Veklury (remdesivir) Dosing in adults weighing < 40kg. Last update: March 23, 2023. Gilead; received March 4, 2024.