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PUBLIC HEALTH ADVISORY

To:	All Health Care
From:	Dr. Isaac Benowitz, Maine CDC State Epidemiologist
Subject:	**Expanded U.S. FDA Approval of Remdesivir for COVID-19 Treatment**
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Expanded U.S. FDA Approval of Remdesivir for COVID-19 Treatment

I. Summary

On January 21, 2022, the U.S. Food and Drug Administration (FDA) granted full approval to the antiviral drug remdesivir (Veklury®) to treat non-hospitalized patients 12 years of age and older with mild-to-moderate COVID-19 disease who are at high risk of hospitalization. This expanded approval provides another treatment option to reduce the risk of hospitalization in high-risk patients. The use of remdesivir was previously limited to patients requiring hospitalization, and treatment outside the hospital was off-label. Remdesivir's manufacturer, Gilead Sciences, Inc., indicates that it has been able to meet demand for this drug. *In vitro* data suggest that remdesivir remains active against the Omicron variant of SARS-CoV-2.[1]

The expanded indication allows remdesivir to be administered in qualified outpatient settings that can administer daily intravenous (IV) infusions over three consecutive days. The FDA also expanded remdesivir's pediatric Emergency Use Authorization (EUA) to include non-hospitalized pediatric patients younger than 12 years of age (over 3.5 kg) who are at high risk of disease progression.

II. Use of Remdesivir

A. Clinical Trial Data

The FDA's expanded approval, the pediatric EUA expansion, and the recently updated National Institutes of Health (NIH) Treatment Guidelines for COVID-19 are based on results from the PINETREE Phase 3 randomized, double-blind, placebo-controlled trial.[2] That trial evaluated the safety and efficacy of a three-day course of IV remdesivir for the treatment of COVID-19 in non-hospitalized patients at high risk for disease progression. An analysis of 562 participants randomly assigned in a 1:1

ratio to receive remdesivir or placebo found that treatment with remdesivir resulted in a statistically significant 87% reduction in risk for the composite primary endpoint of COVID-19 related hospitalization or all-cause death by day 28 (0.7% [2/279]) compared with placebo (5.3% [15/283]) p=0.008. There were no deaths in either group. The safety profile was similar between remdesivir and placebo, with the most common treatment emergent adverse events (≥5%) in patients taking remdesivir being nausea and headache. This study found that the reduction in hospitalization rates was similar to that achieved by using anti-SARS-CoV-2 monoclonal antibody-based therapy.

B. Administration

The treatment course of remdesivir should be initiated as soon as possible after the diagnosis of symptomatic COVID-19 has been made and within 7 days of symptom onset. 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 recommended dosage in adults and pediatric patients 12 years of age and older and weighing at least 40 kg is a single loading dose of remdesivir 200 mg on Day 1 followed by once-daily maintenance doses of remdesivir 100 mg on Day 2 and Day 3 via intravenous infusion. Administer remdesivir via intravenous (IV) infusion over 30 to 120 minutes.

III. Additional Pediatric Authorization

FDA also revised remdesivir's Emergency Use Authorization (EUA) to additionally authorize the drug for 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 SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization of death.

IV. Recommendations for Healthcare Providers

- As with all therapeutics, the best use of therapeutics includes an appropriate clinical assessment and an up-to-date and informed risk-benefit discussion to address any questions or concerns from patients.
- Obtain further information on clinical use of products through NIH's COVID-19 Treatment Guidelines, the Assistant Secretary for Preparedness and Response Public Health Emergency COVID-19 Therapeutics site, and through professional societies such as IDSA's Guidelines on the Management of Patients with COVID-19.
- Continue to encourage COVID-19 vaccination, including booster vaccination.

For More Information

- Remdesivir labeling
- Remdesivir EUA
- Omicron Variant: What You Need to Know | CDC
- COVID-19 Treatment Guidelines: What's New
- COVID-19 Treatment Guidelines: Antiviral Therapy
- NIH Statement on Therapies for High-Risk, Nonhospitalized Patients | COVID-19 Treatment Guidelines

References

1. Vangeel L, De Jonghe S, Maes P, et al. Remdesivir, Molnupiravir and Nirmatrelvir remain active against SARS-CoV-2 Omicron and other variants of concern. bioRxiv 2021. https://doi.org/10.1101/2021.12.27.474275
2. Gottlieb RL, Vaca CE, Paredes R, et al.; GS-US-540-9012 (PINETREE) Investigators. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. N Engl J Med. 2021 Dec 22. https://www.nejm.org/doi/full/10.1056/NEJMoa2116846