

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

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# The Medical Letter®

## on Drugs and Therapeutics

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### COVID-19 UPDATES

#### Remdesivir (*Veklury*) in High-Risk Outpatients with COVID-19

The IV antiviral drug remdesivir (*Veklury* – Gilead) has been available for treatment of COVID-19 in hospitalized patients since 2020.<sup>1</sup> Now, the FDA has approved remdesivir for treatment of mild to moderate COVID-19 in outpatients  $\geq 12$  years old who weigh  $\geq 40$  kg and are at high risk for progression to severe disease, including hospitalization or death; they also issued an Emergency Use Authorization (EUA) allowing its use in any other high-risk outpatient who weighs  $\geq 3.5$  kg.<sup>2,3</sup>

**CLINICAL STUDIES** – FDA approval of remdesivir for use in outpatients was based on the results of a double-blind trial in 562 nonhospitalized, SARS-CoV-2-positive adults who had developed symptoms of COVID-19  $\leq 7$  days previously and had one or more risk factors for progression to severe COVID-19 (e.g., age  $\geq 60$  years, obesity, hypertension, diabetes). Patients were randomized to receive 3 days of IV treatment with remdesivir (200 mg on day 1 and 100 mg on days 2 and 3) or placebo. Hospitalization related to COVID-19 by day 28 occurred significantly less often with the active drug (0.7% vs 5.3% with placebo; HR 0.13 [95% CI 0.03-0.59]; NNT 21.8). No deaths occurred by day 28 in either group.<sup>4</sup>

No clinical trial data are available on use of remdesivir in patients aged  $< 12$  years or weighing  $< 40$  kg. Authorization of the drug for use in such patients was based on extrapolation of clinical and pharmacokinetic data from studies in adults.<sup>5</sup>

**DOSAGE AND ADMINISTRATION** – The recommended dosage of remdesivir in high-risk outpatients weighing  $\geq 40$  kg is 200 mg IV on day 1 and 100 mg IV on days 2 and 3. For patients weighing  $< 40$  kg, the recommended dose is 5 mg/kg on day 1 and 2.5 mg/kg on days 2 and 3. The drug should be infused over 30-120 minutes. Treatment should be started within 7 days of symptom onset. Patients receiving remdesivir should be monitored for hypersensitivity reactions during administration of the drug and for 1 hour after completion of each infusion. Remdesivir is not recommended for use in patients with an eGFR  $< 30$  mL/min (or, in full-term neonates 7-28 days old, a serum creatinine level  $\geq 1$  mg/dL).<sup>5</sup>

**RECOMMENDATIONS** – The NIH recommends a 3-day course of IV remdesivir as a third-line option for treatment of mild to moderate COVID-19 in high-risk outpatients  $\geq 12$  years old who weigh  $\geq 40$  kg; it should be used if *Paxlovid* (nirmatrelvir/ritonavir) and sotrovimab are inappropriate or unavailable. Remdesivir is the only drug that is currently authorized by the FDA for treatment of COVID-19 in persons aged  $< 12$  years or weighing  $< 40$  kg.<sup>6,7</sup> ■

1. Remdesivir (*Veklury*) for COVID-19. *Med Lett Drugs Ther* 2020; 62:186.
2. FDA News Release. FDA takes actions to expand use of treatment for outpatients with mild-to-moderate COVID-19. January 21, 2022. Available at: <https://bit.ly/3AwPkj9>. Accessed January 28, 2022.
3. CDC. Underlying medical conditions associated with higher risk for severe COVID-19: information for healthcare providers. October 14, 2021. Available at: <https://bit.ly/3tWR8Rg>. Accessed January 28, 2022.
4. RJ Gottlieb et al. Early remdesivir to prevent progression to severe Covid-19 in outpatients. *N Engl J Med* 2022; 386:305.
5. FDA. Fact sheet for health care providers. Emergency Use Authorization (EUA) of *Veklury* (remdesivir) for the treatment of coronavirus disease 2019 (COVID-19) in pediatric patients. January 2022. Available at: <https://bit.ly/35ok8aw>. Accessed January 28, 2022.
6. NIH. The COVID-19 Treatment Guidelines Panel's statement on therapies for high-risk, nonhospitalized patients with mild to moderate COVID-19. January 19, 2022. Available at: <https://bit.ly/3fyk4jC>. Accessed January 28, 2022.
7. COVID-19 updates: NIH outpatient treatment guidelines. *Med Lett Drugs Ther* 2022; 64:32.

## NIH Outpatient Treatment Guidelines

NIH guidelines<sup>1</sup> now recommend that high-risk outpatients with mild to moderate COVID-19 who are  $\geq 12$  years old and weigh  $\geq 40$  kg receive antiviral treatment with (in order of preference) a 5-day course of oral nirmatrelvir with ritonavir (*Paxlovid*),<sup>2</sup> a single IV infusion of the monoclonal antibody sotrovimab,<sup>3</sup> a 3-day course of IV remdesivir (*Veklury*),<sup>4</sup> or (in adults) a 5-day course of oral molnupiravir.<sup>5</sup> Nirmatrelvir/ritonavir and sotrovimab are preferred over remdesivir mainly because of logistical concerns associated with IV infusion of remdesivir on 3 consecutive days. Molnupiravir should only be used when *Paxlovid*, sotrovimab, and remdesivir are inappropriate or unavailable because it is less effective than these preferred alternatives. The monoclonal antibody combinations casirivimab plus imdevimab (*REGEN-COV*) and bamlanivimab plus etesevimab are not currently authorized for use in the US because they lack activity against the Omicron variant of SARS-CoV-2.<sup>6</sup> ■

1. Remdesivir (Veklury) for COVID-19. *Med Lett Drugs Ther* 2020; 62:186.
2. Paxlovid for treatment of COVID-19. *Med Lett Drugs Ther* 2022; 64:9.
3. An EUA for sotrovimab for treatment of COVID-19. *Med Lett Drugs Ther* 2021; 63:97.
4. COVID-19 updates: Remdesivir (Veklury) in high-risk outpatients with COVID-19. *Med Lett Drugs Ther* 2022; 64:31.
5. Molnupiravir for treatment of COVID-19. *Med Lett Drugs Ther* 2022; 64:10.
6. FDA Statement. Coronavirus (COVID-19) update: FDA limits use of certain monoclonal antibodies to treat COVID-19 due to the omicron variant. January 24, 2022. Available at: <https://bit.ly/3GVGWR>. Accessed January 28, 2022.

### Additional Content Available Online: COVID-19 Tables/Charts

Please check our website for the latest information on COVID-19, including our continuously updated tables/charts on treatments, vaccines, and dosing recommendations. Available at: [www.medicalletter.org/drugs-for-covid-19](http://www.medicalletter.org/drugs-for-covid-19).

## Moderna COVID-19 Vaccine (*Spikevax*) Gains Full Licensure

The FDA has licensed the mRNA-based COVID-19 vaccine manufactured by Moderna (*Spikevax*) for use as a 2-dose primary series to prevent COVID-19 in adults.<sup>1,2</sup> It is the second COVID-19 vaccine to receive full licensure in the US; the mRNA-based vaccine manufactured by Pfizer/BioNTech (*Comirnaty*) was licensed in 2021.

*Spikevax* remains available under an FDA Emergency Use Authorization (EUA) for use as a 3-dose primary series in immunocompromised adults and for booster immunization.<sup>3</sup> A summary of indications for *Spikevax* can be found in Table 1. ■

**Table 1. Indications and Dosage Regimens for *Spikevax***

Indication <sup>1</sup>	Dosage
Primary immunization <sup>2</sup>	100 mcg (0.5 mL) IM at 0 and 4 weeks
Additional primary dose for immunocompromised persons <sup>3</sup>	100 mcg (0.5 mL) IM $\geq 4$ weeks after second primary dose
Booster dose after a Moderna or Pfizer/BioNTech primary series <sup>3</sup>	50 mcg (0.25 mL) IM $\geq 5$ months after last primary dose
Booster dose after a Johnson & Johnson primary dose <sup>3</sup>	50 mcg (0.25 mL) IM $\geq 2$ months after primary dose

1. *Spikevax* is indicated for use in adults.
2. FDA-licensed for this indication.
3. Available under an FDA Emergency Use Authorization (EUA) for this indication.

1. FDA News Release. Coronavirus (COVID-19) update: FDA takes key action by approving second COVID-19 vaccine. January 31, 2022. Available at: <https://bit.ly/3L3Rllq>. Accessed February 3, 2022.
2. FDA authorizes Moderna COVID-19 vaccine. *Med Lett Drugs Ther* 2021; 63:9.
3. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). January 31, 2022. Available at: <https://bit.ly/3nosylA>. Accessed February 3, 2022.

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