

## FDA NEWS RELEASE

# COVID-19 Update: FDA Broadens Emergency Use Authorization for Veklury (remdesivir) to Include All Hospitalized Patients for Treatment of COVID-19

**For Immediate Release:**

August 28, 2020

Today, as part of its ongoing efforts to fight COVID-19, the U.S. Food and Drug Administration broadened the scope of the existing emergency use authorization (EUA) (</media/137564/download>) for the drug Veklury (remdesivir) to include treatment of all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19, irrespective of their severity of disease.

In May 2020 (</news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>), the FDA issued an EUA that authorized Veklury for the treatment of hospitalized adult and pediatric patients with severe COVID-19. As noted in the initial issuance of the EUA, the emergency use of Veklury was limited to those patients with severe disease, which was defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator.

Today, based on the Agency's ongoing review of the EUA, including its review of the totality of scientific information now available, the FDA has determined that it is reasonable to believe Veklury may be effective for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients. The Agency's review has also concluded that the known and potential benefits of Veklury outweigh the known and potential risks for these uses.

**“The FDA continues to make safe and potentially helpful treatments for COVID-19 available as quickly as possible in order to help patients. The data to support today's action are encouraging. The data show that this treatment has the potential to help even more hospitalized patients who are suffering from the effects of this devastating virus,”** said FDA Commissioner Stephen M. Hahn, M.D. **“We are working with drug developers to conduct randomized clinical trials to further study the**

**safety and effectiveness of a number of potential therapies (/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap) for COVID-19.”**

*Regulatory and Scientific Basis for Emergency Use*

Under the law, the FDA may revise an emergency use authorization, as appropriate, based on additional public health considerations, such as new data. Based on the Agency’s ongoing review of the EUA for Veklury, including its review of the totality of scientific information now available, the Agency is revising the EUA to expand the scope of the authorized uses to include the treatment of hospitalized adult and pediatric patients, irrespective of their disease severity. The expansion of the scope of the EUA to include hospitalized patients with mild or moderate COVID-19 is supported by the Agency’s analysis of additional data from two randomized, controlled clinical trials that included patients with mild or moderate disease.

One randomized, double-blind, placebo-controlled clinical trial (<https://clinicaltrials.gov/ct2/show/NCT04280705>) (ACTT-1), conducted by the National Institute of Allergy and Infectious Diseases, evaluated how long it took for subjects to recover from COVID-19 within 29 days of being treated. The trial looked at 1,062 hospitalized subjects with mild, moderate and severe COVID-19 who received Veklury (n=541) or placebo (n=521), plus standard of care. Recovery was defined as either being discharged from the hospital or being hospitalized but not requiring supplemental oxygen and no longer requiring ongoing medical care. The median time to recovery from COVID-19 was 10 days for the Veklury group compared to 15 days for the placebo group, a statistically significant difference. Overall, the odds of clinical improvement at Day 15 were also statistically significantly higher in the Veklury group when compared to the placebo group. In hospitalized patients with mild to moderate disease, the results for time to recovery as well as the odds of improvement at Day 15 numerically favored the Veklury group and were consistent with the overall study results.

A separate randomized, open-label multi-center clinical trial (<https://clinicaltrials.gov/ct2/show/NCT04292730>) (Study GS-US-540-5774) of hospitalized adult subjects with moderate COVID-19 compared treatment with Veklury for five days (n=191) and treatment with Veklury for 10 days (n=193) with standard of care (n=200). Researchers evaluated the clinical status of subjects on Day 11. Overall, the odds of a subject’s COVID-19 symptoms improving were statistically significantly higher in the five-day Veklury group at Day 11 when compared to those receiving only standard of care. The odds of improvement with the 10-day treatment group when compared to those receiving only standard of

care were numerically favorable, but not statistically significantly different. At Day 28, mortality was less than or equal to 2 percent in all treatment groups.

Limitations of this trial included the open-label design.

Important information about using Veklury in treating COVID-19 is available in fact sheets to health care providers (</media/137566/download>) and patients (</media/137565/download>), which include dosing instructions, potential side effects and drug interactions. Possible side effects include: increased levels of liver enzymes, which may be a sign of inflammation or damage to cells in the liver; and infusion-related reactions, which may include low blood pressure, nausea, vomiting, sweating, and shivering.

*The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.*

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## Related Information

- [Frequently Asked Questions on the Emergency Use Authorization for Veklury \(remdesivir\) for Hospitalized COVID-19 Patients](#) (</media/137574/download>)
- [Remdesivir EUA Letter of Authorization](#) (</media/137564/download>)

- [Emergency Use Authorization: Therapeutics \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs\)](/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs)
- [Coronavirus Treatment Acceleration Program \(CTAP\) \(/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap\)](/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap)
- [Coronavirus Disease \(COVID-19\) \(/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19\)](/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)

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