

Frequently Asked Questions for Veklury (remdesivir)

Q. Is Veklury (remdesivir) approved by FDA to treat COVID-19?

A. On October 22, 2020, FDA approved the new drug application (NDA) 214787 for Veklury (remdesivir) for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization.

On January 21, 2022, FDA approved a supplement to the NDA (sNDA) expanding the indication for Veklury to also include the treatment of COVID-19 in non-hospitalized adults and pediatric patients (12 years of age and older and weighing at least 40 kg), with positive results of direct SARS-CoV-2 viral testing, with mild-to-moderate COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Q. Is Veklury available for use under an emergency use authorization for pediatric patients not covered under the approved indication?

A. Veklury is authorized under an [emergency use authorization \(EUA\)](#) for the treatment of COVID-19 in pediatric patients weighing 3.5 kg to less than 40 kg *or* pediatric patients less than 12 years of age and weighing at least 3.5 kg, with positive results of direct SARS-CoV-2 viral testing, and who 1) *are* hospitalized, or 2) *are not* hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

For additional information on the authorized use of Veklury under the EUA, refer to the [Fact Sheet for Healthcare Providers](#).

Clinical trials assessing the safe and effective use of Veklury in pediatric populations remain ongoing.

Q. How is high risk defined under the EUA?

A. Information about conditions that place a patient with mild-to-moderate COVID-19 at increased risk for disease progression or death can be found at the Centers for Disease Control and Prevention site: [People with Certain Medical Conditions](#), specifically under the *Additional Information on Children and Teens* section. Health care providers should consider the benefit-risk for an individual patient.

Q. What is the difference between an Emergency Use Authorization (EUA) and an FDA approval?

A. Under section 564 of the Federal Food, Drug & Cosmetic Act (FD&C Act), the FDA may, pursuant to a determination and declaration by the HHS Secretary, authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, the FDA must determine, among other things, that the product *may* be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits outweigh the known and potential risks for the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure. EUAs remain authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the authorized product under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

FDA approves NDAs under section 505(c) of the FD&C Act. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical that is not a biologic¹ for sale and marketing in the U.S. In approving an NDA, FDA reviewers must determine, among other things, that the drug is safe and effective for its labeled use(s), and that the benefits of the drug outweigh the risks; that the drug's labeling (package insert) is appropriate; and that the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. The statutory standard for an NDA approval requires substantial evidence of effectiveness, which is a higher level of evidence of effectiveness than required for an EUA.

Q. What data supports FDA's determination that Veklury is safe and effective for use in certain adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19?

A. Full information regarding the data and evidence supporting the original approval of Veklury on October 22, 2020 can be found in the [Combined Cross-Discipline Team Leader, Division Director, and ODE Director Summary Review](#).

The approval of the sNDA for Veklury on January 21, 2022, for use in certain non-hospitalized patients is supported by a randomized, placebo-controlled [clinical trial](#) that included 562 non-hospitalized patients with mild-to-moderate COVID-19 who were at high risk for progression to severe COVID-19, including hospitalization or death. The main outcome measured in the trial was whether a patient was hospitalized for any COVID-19 related reason or died from any reason within 28 days of treatment. Overall, 2 of 279 patients who received Veklury (0.7%) required COVID-19-related hospitalization compared to 15 of 283 patients who received a placebo (5.3%). There were no deaths in either group.

Q. Are there side effects of Veklury?

A. Possible side effects of Veklury include:

- Hypersensitivity reactions, including infusion-related and anaphylactic reactions. Hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been seen during a Veklury infusion or around the time Veklury was given. Signs and symptoms may include: changes in blood pressure and heart rate, low blood oxygen level, fever, shortness of breath, wheezing, swelling (e.g. lips, around the eyes, under the skin), rash, nausea, sweating, and shivering.
- Increases in levels of liver enzymes, seen in liver blood tests. Increases in levels of liver enzymes have been seen in people who have received Veklury, which may be a sign of liver injury.

These are not all the possible side effects of Veklury. FDA maintains a system of safety surveillance and risk assessment programs to identify adverse events that have occurred following authorization or approval of the product.

Q. Is there a requirement for health care providers to report adverse events when Veklury is administered as part of the EUA?

A. Yes, FDA is requiring health care providers who prescribe Veklury to pediatric patients under the EUA to report all serious adverse events and medication errors potentially related to Veklury through FDA's [MedWatch Adverse Event Reporting](#) program. Providers can complete and submit the report [online](#); or download and complete the [form](#), then submit it via fax at 1-800-FDA-0178. This requirement is outlined

¹ Biologics are approved upon submission and review of a biologic license application (BLA).

in the EUA's [Fact Sheet for Healthcare Providers](#). A copy of the MedWatch form submitted to FDA should also be provided to Gilead.

Q. Are there post-marketing safety reporting requirements for the approved Veklury?

A. FDA regulations do not require mandatory reporting of adverse events by health care providers for approved products. However, health care providers can voluntarily report an adverse event by completing and submitting the report [online](#); or by downloading and completing the [form](#), then submitting it via fax at 1-800-FDA-0178. Voluntary reporting by health care providers can help FDA identify unknown risks for approved products.

Applicants of NDAs and other responsible parties are subject to regulatory requirements regarding postmarketing safety reporting. For further information, see 21 CFR 314.80 (Postmarketing reporting of adverse drug experiences) or FDA's guidance for industry: [Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines](#).

Q. Do patient outcomes need to be reported under the EUA?

A. No, reporting of patient outcomes is not required under the EUA. However, reporting of all medication errors and serious adverse events considered to be potentially related to Veklury occurring during Veklury treatment is required.

Q. Can Veklury be used to prevent COVID-19?

A. The safety and efficacy of Veklury for the prevention of COVID-19 have not been established and it is not FDA-approved or authorized for this use.

Q. Is Veklury expected to work against the Omicron variant?

A. Although further testing is being done, the available data suggest Veklury is expected to work against the Omicron (B.1.1.529) variant. Veklury works against the SARS-CoV-2 virus by interfering with the process of making more virus and inhibiting viral replication inside infected cells. Based on laboratory testing, and FDA's knowledge of the way that Veklury works against the SARS-CoV-2 virus, Veklury is expected to be active against SARS-CoV-2 variants that have circulated at a high frequency to date, including against the Omicron variant. The part of the virus that Veklury targets is not expected to be affected by the changes in the variants that have circulated so far (e.g., the Delta variant) or are currently circulating, such as the Omicron variant.

Q. There is a warning about drug interactions between hydroxychloroquine sulfate/chloroquine phosphate and Veklury in the healthcare provider Fact Sheet and Veklury's prescribing information. If I take hydroxychloroquine sulfate for a chronic condition, does this mean I should not take Veklury?

A. There is the potential for Veklury to not work as well to treat COVID-19 when it is taken with hydroxychloroquine sulfate (HCQ) or chloroquine phosphate (CQ). FDA recommends against taking the drugs together. If you are taking HCQ or CQ, discuss your options and specific situation with your health care provider.

Q. Can health care providers share the patient/caregiver Fact Sheet electronically?

A. Under the authorization, Gilead must make available the authorized Fact Sheets on its website at: www.gilead.com/remdesivir. Health care facilities and health care providers must ensure that fact

sheets are made available to parents and caregivers prior to administration of Veklury through “appropriate means.” Electronic delivery of the Fact Sheet is an appropriate means.

Q. Does FDA have concerns about compounding remdesivir?

A. Compounded drugs are not FDA-approved. This means FDA cannot verify the safety, effectiveness, or quality of compounded drugs. Because they are subject to a lower regulatory standard, compounded drugs should only be used to meet the needs of patients whose medical needs cannot be met by an FDA-approved drug. The agency recommends the FDA-approved drug Veklury (remdesivir) be used to treat patients who are prescribed the drug remdesivir.

FDA is concerned that it may be difficult to source active ingredient of appropriate quality and compound quality remdesivir products because of the complexity of producing a stable finished drug. The agency is concerned patients may receive substandard or low-quality compounded remdesivir drugs which could result in patient harm.

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