Veklury®
remdesivir 100 MG FOR INJECTION

Product information

VEKLURY® (remdesivir) 100 mg for injection, lyophilized powder

NDC[1]

61958-2901-2

VEKLURY lyophilized formulation is available for purchase. Please continue to utilize all unexpired, unopened vials of VEKLURY, whether or not the vial includes the brand name VEKLURY or is labeled remdesivir for use under EUA.

WAC[2]

$520 per vial
The information listed reflects the WAC price reported by First Databank™ (FDB) as of October 2020.

Dosage form and strength[1]

100 mg, available as a sterile, preservative-free, white to off-white to yellow lyophilized powder in single-dose vial for reconstitution

How supplied[1]

Supplied as a single-dose vial containing a sterile, preservative-free, white to off-white to yellow lyophilized powder. It requires reconstitution and further dilution prior to administration by intravenous infusion.

Discard unused portion.

The container closure is not made with natural rubber latex.

NDC = National Drug Code; WAC = wholesale acquisition cost.

For information on variations in carton and vial labeling of VEKLURY, as well as emergency use in hospitalized pediatric patients <12 years of age weighing at least 3.5 kg or weighing 3.5 kg to <40 kg, please see the Dear HCP letter available here.

Indication

VEKLURY is indicated for the treatment of adults and pediatric patients ≥12 years old and weighing ≥40 kg requiring hospitalization for COVID-19. VEKLURY should only be administered in a hospital or healthcare setting capable of providing acute care comparable to inpatient hospital care.

Important Safety Information

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Please see full Prescribing Information for VEKLURY.

Product information (cont.)

	VEKLURY® (remdesivir) 100 mg for injection, lyophilized powder
Storage and handling[1]	Do not reuse or save reconstituted or diluted VEKLURY for future use. These products contain no preservative; therefore, partially used vials should be discarded.
	Store VEKLURY for injection, 100 mg vials below 30 °C (below 86 °F) until required for use. After reconstitution, use vials immediately to prepare diluted solution. Dilute the reconstituted solution in 0.9% sodium chloride injection, USP within the same day as administration. The diluted VEKLURY solution in the infusion bags can be stored up to 24 hours at room temperature (20-25 °C [68-77 °F]) prior to administration or 48 hours at refrigerated temperature (2-8 °C [36-46 °F]).

ICD-10-CM/PCS codes for VEKLURY[3]

Please refer to specific payer and state guidelines for direction on appropriate code selection. The following types of codes may be used on an inpatient claim form:

- International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes
- International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) procedure codes

For dates of service beginning April 1, 2020, the Centers for Disease Control and Prevention issued a code to capture confirmed cases of COVID-19. Hospitals may report ICD-10-CM diagnosis code **U07.1** as a principal or secondary diagnosis for a claim that they deem is appropriate when a COVID-19 diagnosis is confirmed.

For discharges on or after August 1, 2020, the Centers for Medicare & Medicaid Services announced that hospitals may report the following ICD-10-PCS procedure codes for a claim they deem is appropriate.

Code	Description
XW033E5	Introduction of VEKLURY Anti-infective into *Peripheral* Vein, Percutaneous Approach, New Technology Group 5
XW043E5	Introduction of VEKLURY Anti-infective into *Central* Vein, Percutaneous Approach, New Technology Group 5

The information provided is for reference only; it is not advice about how to code, complete, or submit any claim for payment. Please refer to specific payer and state guidelines for direction on appropriate code selection as codes may change and hospitals must make their own determination. It is the responsibility of the health provider to confirm the appropriate coding required.

Important Safety Information (cont.)

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY. Monitor patients under close medical supervision for hypersensitivity reactions during and following administration of VEKLURY. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time ≤120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).

Please see full Prescribing Information for VEKLURY.

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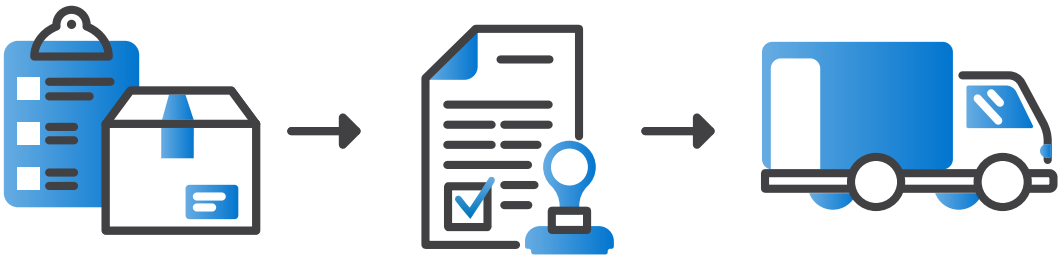
VEKLURY® distribution and access



Supplier

Gilead utilizes ABC Specialty Division, Cardinal Specialty, and McKesson Plasma and Biologics as the distributors of VEKLURY®.

Ordering process

Hospitals can place orders with any of the 3 distributors by calling directly:
ABC, 1-800-746-6273;
Cardinal, 1-855-855-0708;
McKesson, 1-877-625-2566.
The distributor will confirm order quantity to be shipped to hospitals.

Shipment

The distributor will ship directly to hospitals.

To help avoid potential drug shortage, hospitals should continue to use all unexpired, unopened vials of Gilead's remdesivir—whether or not the vial includes the brand name VEKLURY or is labeled for use under EUA.

ABC = AmerisourceBergen Corporation.

Important Safety Information (cont.)

Warnings and precautions (cont.)

- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Drug interactions

- Drug interaction trials of VEKLURY and other concomitant medications have not been conducted in humans.

Please see full Prescribing Information for VEKLURY.

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Important Safety Information (cont.)

Dosage and administration

- **Dosage:** For adults and pediatric patients ≥12 years old and weighing ≥40 kg: 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2 administered only via intravenous infusion over 30 to 120 minutes.
- **Treatment duration:** For patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO): 5 days; may be extended up to 5 additional days (10 days total) if clinical improvement is not observed. For patients requiring invasive mechanical ventilation and/or ECMO: 10 days.
- **Testing prior to and during treatment:** Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** VEKLURY is not recommended in individuals with eGFR <30 mL/min.
- **Dose preparation and administration:** See full Prescribing Information.

Pregnancy and lactation

- **Pregnancy:** There are insufficient human data on the use of VEKLURY during pregnancy. Pregnant women hospitalized with COVID-19 are at risk for serious morbidity and mortality. VEKLURY should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.
- **Lactation:** It is not known whether VEKLURY can pass into breast milk. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Please see full Prescribing Information for VEKLURY.

References: 1. VEKLURY. Prescribing Information. Gilead Sciences, Inc.; 2021. **2.** FDB Medknowledge™. South San Francisco, CA: First Databank™; 2020. **3.** Centers for Medicare & Medicaid Services. ICD-10 MS-DRGs version 37.2 effective August 01, 2020. https://www.cms.gov/files/document/icd-10-ms-drgs-version-372-effective-august-01-2020.pdf

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