Veklury® remdesivir 100 MG FOR INJECTION

LEADING THE WAY

Real-World Readmission Study

A retrospective observational study published in the *Journal of Comparative Effectiveness Research*

VEKLURY® use and hospital readmission outcomes

Mozaffari E, Chandak A, Gottlieb RL, et al. Treatment of patients *J Comp Eff Res*. 2024;13(4):e230131. doi:10.57264/cer-2023-0131

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (birth to <18 years of age weighing ≥1.5 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

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 additional Important Safety Information throughout and full Prescribing Information here.

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VEKLURY® shortened recovery time in patients hospitalized with COVID-19[1,2]

5 DAYS SHORTER RECOVERY TIME WITH VEKLURY

In the ACTT-1 study,[1]

Median 10 days to recovery with VEKLURY vs 15 days with placebo; recovery rate ratio: 1.29 (95% CI, 1.12 to 1.49), $P < 0.001$

- The primary endpoint was time to recovery within 29 days after randomization based on an 8-point ordinal scale

Adverse reaction frequency was comparable between VEKLURY and placebo[1]

- All adverse reactions (ARs), Grades ≥3: 41 (8%) with VEKLURY vs 46 (9%) with placebo; serious ARs: 2 (0.4%)* vs 3 (0.6%); ARs leading to treatment discontinuation: 11 (2%)† vs 15 (3%)

ACTT-1 study design: ACTT-1 was a randomized, double-blind, placebo-controlled, phase 3 clinical trial in hospitalized adult patients with confirmed SARS-CoV-2 infection and mild, moderate, or severe COVID-19, who received VEKLURY (n=541) or placebo (n=521) for up to 10 days. Recovery was defined as patients who were no longer hospitalized or hospitalized but no longer required ongoing medical care for COVID-19.[1]

*Seizure (n=1), infusion-related reaction (n=1).
†Seizure (n=1), infusion-related reaction (n=1), transaminases increased (n=3), ALT increased and AST increased (n=1), GFR decreased (n=2), acute kidney injury (n=3).

IMPORTANT SAFETY INFORMATION (cont'd)

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; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).
- **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.

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Real-World Study

Patients treated with VEKLURY® were significantly less likely to be readmitted across variant periods[3]

Study overview[1]

A large, real-world, retrospective observational study examined 30-day readmission to the same hospital after COVID-19 hospitalization in adult patients (≥18 years of age) who were treated with VEKLURY vs those not treated with VEKLURY across variant periods: pre-Delta (5/2020–4/2021), Delta (5/2021–11/2021), and Omicron (12/2021–4/2022). The study period was from May 2020 through April 2022 and covered the pre-BA4/5 variant period.

The **main outcomes** were 30-day, COVID-19–related* and all-cause† readmission after being discharged alive from the index hospitalization for COVID-19 between May 1, 2020, and April 30, 2022.

- Data were examined using multivariate logistic regression. The model adjusted for age, corticosteroid use, variant period, Charlson Comorbidity Index (CCI), maximum supplemental oxygen requirements, and ICU admission during COVID-19 hospitalization
- VEKLURY-treated patients received at least 1 dose of VEKLURY during the index COVID-19 hospitalization‡
- This study was sponsored by Gilead Sciences, Inc.

Data source

PINC AI™ Healthcare Database: This US hospital–based, service-level, all-payer (commercial, Medicare, Medicaid, others) database **covered approximately 25% of all US hospitalizations from 48 states**.[3,4]

Study population

- **440,601 patients** with a primary diagnosis of COVID-19 and who were discharged alive
- **248,785 VEKLURY patients** were compared to **191,816 non-VEKLURY** patients

The patient population included a broad range of:

- Comorbidities
- Supplemental oxygen requirements
- Ages
- Concomitant medications used§

See additional study information on the following page ❯

*Defined as readmission with a primary or secondary discharge diagnosis of COVID-19.
†Defined as readmission to the same hospital within 30 days of being discharged alive from the index hospitalization for COVID-19.
‡Refer to the VEKLURY Prescribing Information for dosage and administration recommendations.
§Other treatments administered at baseline for patients (across both study arms) included corticosteroids, tocilizumab, and baricitinib as well as combinations of aforementioned treatments.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see additional Important Safety Information throughout and full Prescribing Information here.

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Real-World Study

Patients treated with VEKLURY® were significantly less likely to be readmitted across variant periods[3] (cont'd)

POPULATION CHARACTERISTICS

Compared to nonreadmitted patients, readmitted patients:

- **Were older:** median 71 years vs 63 years
- **Had more comorbidities:** CCI ≥4: 36% vs 16%
- **Were more likely to have NSOc:** (42% vs 39%) and less likely to be on low-flow oxygen (40% vs 42%)
- **Were less likely to be treated with VEKLURY:** 48% vs 57%
- **Were more likely to have received corticosteroid monotherapy during index hospitalization:** 38% vs 29%

Compared to non-VEKLURY patients, VEKLURY patients:

- **Were younger:** median 62 years vs 64 years
- **Were more likely to have received some level of supplemental oxygen support (any supplemental oxygen support, 1-NSOc):** 70% vs 48%

Study considerations

Real-world studies should be interpreted based on the type and size of the source datasets and the methodologies used to mitigate potential confounding bias. Real-world data should be considered in the context of all available data; results may vary between studies.

Strengths

- Large study population enabled subgroup analyses across variant periods and supplemental oxygen requirements
- Well-defined cohort of patients hospitalized for COVID-19

Limitations

- Potential for residual confounding due to unmeasured variables, including differences in groups that could not be accounted for
- The database did not capture data relating to time from symptom onset, infecting viral lineages, and prehospital care such as other treatments
- Due to the absence of billing charges for supplemental oxygen, some patients who received supplemental oxygen could be misclassified as NSOc
- Patients readmitted to a different hospital were not accounted for

See the study outcomes on the following pages ❯

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration

— Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

NSOc=no supplemental oxygen charges.

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Real-World Study

Patients treated with VEKLURY® had significantly reduced likelihood of readmission[3]

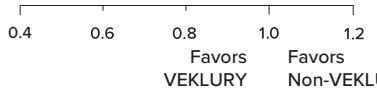
40%

Reduced likelihood of 30-day COVID-19–related readmission was observed with VEKLURY; aOR: 0.60 (95% CI, 0.58 to 0.62), *P* < 0.0001

- 3.0% of VEKLURY patients vs 5.4% of non-VEKLURY patients experienced COVID-19–related readmission within 30 days

Reduction of 30-day COVID-19–related readmission with VEKLURY was consistently observed across variant periods and all supplemental oxygen requirements (May 2020 through April 2022)

	Unadjusted		Adjusted		
	Readmitted patients/ Total number of patients		Likelihood of 30-day COVID-19 readmission aOR with 95% CI	aOR (95% CI)	*P* value
	VEKLURY	Non-VEKLURY			
Overall cohort	7,453/248,785	10,396/191,816		0.60 (0.58 to 0.62)	< 0.0001
Variant period					
Pre-Delta	3,921/122,560	6,656/109,348		0.54 (0.52 to 0.57)	< 0.0001
Delta	2,031/83,178	2,021/44,215		0.61 (0.57 to 0.65)	< 0.0001
Omicron	1,501/43,047	1,719/38,253		0.77 (0.72 to 0.83)	< 0.0001
Maximum oxygenation in index hospitalization					
No supplemental oxygen charges	2,555/73,589	5,883/99,030		0.55 (0.52 to 0.57)	< 0.0001
Low-flow oxygen	3,487/115,923	3,630/68,389		0.61 (0.58 to 0.65)	< 0.0001
High-flow oxygen/NIV	1,301/50,029	795/19,815		0.73 (0.67 to 0.80)	< 0.0001
IMV/ECMO	110/8,974	88/4,582		0.72 (0.54 to 0.97)	0.0301



Patients treated with VEKLURY **not requiring supplemental oxygen showed the greatest reduction in readmission**—45% less likely to be readmitted

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration:**
  - For patients who **are hospitalized**, VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
  - For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.

aOR=adjusted odds ratio ECMO=extracorporeal membrane oxygenation; IMV=invasive mechanical ventilation; NIV=noninvasive ventilation.

Please see additional Important Safety Information throughout and full Prescribing Information here.

Real-World Study

Patients treated with VEKLURY® had significantly reduced likelihood of readmission[3] (cont'd)

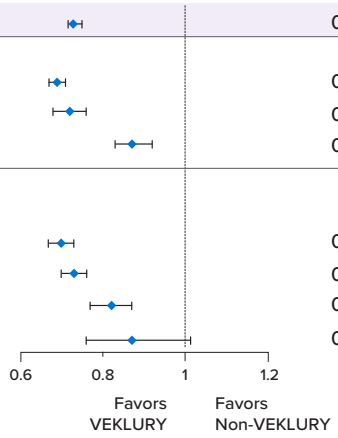
27%

Reduced likelihood of 30-day all-cause readmission was observed with VEKLURY; aOR: 0.73 (95% CI, 0.72 to 0.75), *P* < 0.0001

- 6.3% of VEKLURY patients vs 9.1% of non-VEKLURY patients experienced all-cause readmission within 30 days

30-day, all-cause readmission across variant periods and by maximum oxygenation in index hospitalization (May 2020 through April 2022)

	Unadjusted		Adjusted	
	Readmitted patients/ Total number of patients		Likelihood of 30-day all-cause readmission aOR with 95% CI	aOR (95% CI)	*P* value
	VEKLURY	Non-VEKLURY			
Overall cohort	15,780/248,785	17,437/191,816		0.73 (0.72 to 0.75)	<0.0001
Variant period					
Pre-Delta	7,766/122,560	10,176/109,348		0.69 (0.67 to 0.71)	<0.0001
Delta	4,256/83,178	3,466/44,215		0.72 (0.68 to 0.76)	<0.0001
Omicron	3,758/43,047	3,795/38,253		0.87 (0.83 to 0.92)	<0.0001
Maximum oxygenation in index hospitalization					
No supplemental oxygen	4,806/73,859	9,055/99,030		0.70 (0.67 to 0.73)	<0.0001
Low-flow oxygen	7,025/115,923	6,181/68,389		0.73 (0.70 to 0.76)	<0.0001
High-flow oxygen/NIV	3,379/50,029	1,834/19,815		0.82 (0.77 to 0.87)	<0.0001
IMV/ECMO	570/8,974	367/4,582		0.87 (0.76 to 1.01)	0.0613



- **A statistically significant reduction in the likelihood of 30-day all-cause readmission was observed for all supplemental oxygen levels**, except in the IMV/ECMO group, which did not meet statistical significance due to low sample size in this group[4]

EXPLORE THE ARTICLE PUBLISHED IN THE JOURNAL OF COMPARATIVE EFFECTIVENESS RESEARCH ▶

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration** (cont'd)**:**
  - For patients who are **not hospitalized**, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset for outpatient use.
- **Testing prior to and during treatment:** Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

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IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- **Lactation:** VEKLURY can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from an underlying maternal condition. 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 here.

References: 1. VEKLURY. Prescribing Information. Gilead Sciences, Inc.; 2025. **2.** Beigel JH, Tomashek KM, Dodd LE, et al; ACTT-1 Study Group Members. Remdesivir for the treatment of COVID-19—final report. *N Engl J Med*. 2020;383(19):1813-1826. doi:10.1056/NEJMoa2007764 **3.** Mozaffari E, Chandak A, Gottlieb RL, et al. Treatment of patients hospitalized for COVID-19 with remdesivir is associated with lower likelihood of 30-day readmission: a retrospective observational study. *J Comp Eff Res*. 2024;13(4):e230131. doi:10.57264/cer-2023-0131 **4.** Mozaffari E, Chandak A, Gottlieb RL, et al. Remdesivir is associated with reduced readmission after COVID-19 hospitalization. Poster presented at: 30th Conference on Retroviruses and Opportunistic Infections; February 19-22, 2023; Seattle, WA; poster 558. Accessed March 1, 2025. https://www.croiconference.org/wp-content/uploads/sites/2/posters/2023/RDV_Readmission_analysis_CROI_poster_Feb14_for_upload-133208797557610573.pdf

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