

Veklury[®] (remdesivir) Hospital Readmission

This document is in response to your request for information regarding assessment of hospital readmission following the use of Veklury[®] (remdesivir [RDV]). This response was developed according to principles of evidence-based medicine and contains data from retrospective studies (N≥2000).

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Summary

Real-World Studies on Hospital Readmissions Following Use of RDV

In a retrospective observational study (PINC AI Healthcare Database) that evaluated all-cause and COVID-19–related hospital readmission to the same hospital in patients who had a discharge diagnosis of COVID-19 (N=440,601), relative to no treatment with RDV, treatment with RDV during hospitalization was associated with a statistically significant lower likelihood of 30-day all-cause and COVID-19–related readmission across VOC periods.¹

In a retrospective, observational cohort study in Colorado (N=9760), RDV treatment during the index hospitalization was associated with a decreased risk of both rehospitalization (aHR, 0.77; 95% CI: 0.67–0.89) and ED visit (aHR, 0.79; 95% CI: 0.67–0.92) within 28 days after discharge.²

In a retrospective observational study (HealthVerity Real-Time Insights and Evidence Database) that evaluated hospital readmissions in PS-matched patients who were admitted to the ICU with COVID-19 (N=8044), relative to no treatment with RDV, treatment with RDV during hospitalization was associated with a significantly lower risk of readmission at Days 30, 60, and 90 within each VOC period.³

Real-World Studies on Hospital Readmissions Following Use of RDV

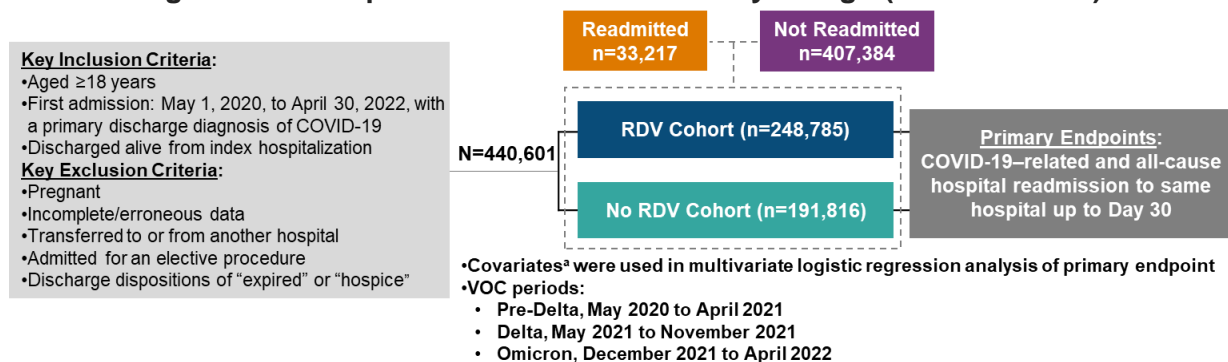
PINC AI Healthcare Database

Study design and demographics¹

A retrospective observational study compared rates of all-cause or COVID-19–related hospital readmission to the same hospital up to Day 30 between patients who did and did

not receive treatment with RDV during their hospitalization and who had a discharge diagnosis of COVID-19. Data were obtained from the US-based PINC AI Healthcare Database and were analyzed overall and by three time periods (pre-Delta, Delta, and Omicron SARS-CoV-2) and maximum oxygenation requirement (no supplemental O₂, low-flow O₂, HFO/NIV, and IMV/ECMO).

Figure 1. Retrospective Observational Study Design (Mozaffari et al)¹



^aCovariates included age, receipt of corticosteroids, VOC period, CCI, maximum O₂ requirement, and ICU admission during hospitalization.

Table 1. Select Baseline Demographics and Disease Characteristics by Receipt of RDV and by Readmission Status Within 30 Days (Mozaffari et al)¹

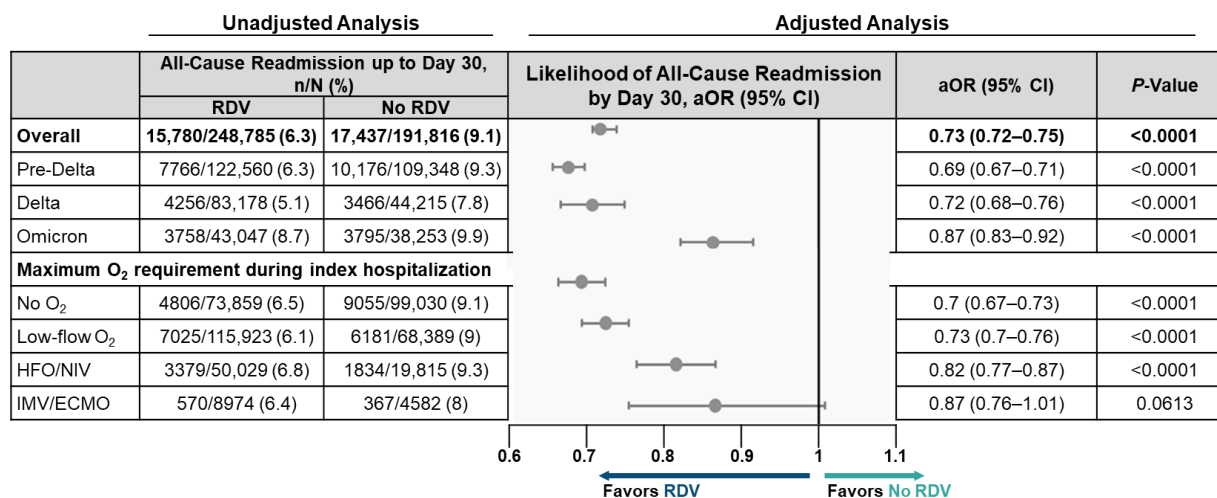
Select Demographics and Characteristics	Overall (N=440,601)	Treatment Cohorts		Readmission Status Cohorts	
		RDV (n=191,816)	No RDV (n=248,785)	Readmitted (n=33,217)	Not Readmitted (n=407,384)
Age, median (IQR), years	63 (51–74)	62 (51–73)	64 (52–76)	71 (60–80)	63 (51–74)
18–49/50–64/≥65, %	22/31/47	23/33/44	21/29/50	11/24/65	23/32/45
Female, %	49	–	–	48	49
CCI, 0/1–3/≥4, %	32/50/18	33/52/15	29/50/21	15/49/36	33/51/16
Maximum O ₂ requirement, ^a no O ₂ /low-flow O ₂ /HFO or NIV/ IMV or ECMO, %	39/42/16/3	30/46/20/4	52/36/10/2	42/40/16/3	39/42/16/3
ICU admission, %	20	22	17	19	20
LOS, median (IQR), days	5 (3–9)	5 (3–8)	5 (3–9)	5 (3–8)	5 (3–9)
VOC period, pre-Delta/Delta/ Omicron, %	–	49/34/17	57/23/20	–	–

^aDefined as the highest level of O₂ required during hospitalization.

Results

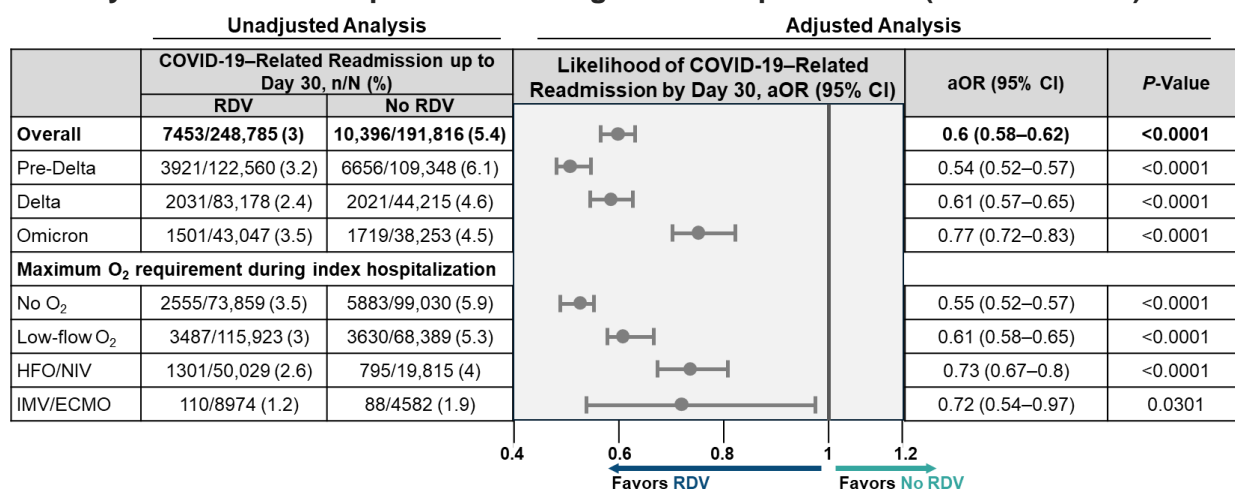
After adjustment for covariates and relative to no treatment with RDV, treatment with RDV during a hospitalization for COVID-19 was associated with a significantly lower likelihood of both all-cause readmission and COVID-19–related readmissions up to Day 30 in the overall cohort and across each VOC period and O₂ requirement level (Figure 2 and Figure 3). RDV was associated with lower rates of all-cause hospital readmission within 30 days (6.3% vs 9.1%) and COVID-19–related readmission within 30 days (3% vs 5.4%) compared with no RDV.¹

Figure 2. All-Cause Readmissions Up to Day 30: Overall, by VOC Periods, and by Maximum O₂ Requirement During Index Hospitalization (Mozaffari et al)¹



Note: ORs were adjusted using the following covariates: age group, use of corticosteroids, VOC period, CCI, maximum O₂ requirement, and ICU stay during hospitalization.

Figure 3. COVID-19–Related Readmissions Up to Day 30: Overall, by VOC Periods, and by Maximum O₂ Requirement During Index Hospitalization (Mozaffari et al)¹



Note: ORs were adjusted using the following covariates: age group, use of corticosteroids, VOC period, CCI, maximum O₂ requirement, and ICU stay during hospitalization.

Follow-up analysis through April 2023⁴

An updated analysis of data through April 2023 included 327,514 patients who received RDV and 262,979 who did not receive RDV. In an unadjusted analysis, and relative to no RDV treatment, patients treated with RDV had a lower all-cause readmission rate (7.7% vs 10.1%) and a lower COVID-19–related readmission rate (3.6% vs 5.8%). After adjusting for covariates, and relative to no RDV, RDV was associated with a lower likelihood of all-cause 30-day readmission (aOR, 0.76; 95% CI: 0.75–0.78; *P*<0.0001) and COVID-19–related readmission (aOR, 0.63; 95% CI: 0.61–0.65; *P*<0.0001). Similar benefits were observed among patients with no supplemental O₂ and with any supplemental O₂ requirement.

Colorado Retrospective, Observational Cohort Study²

Study design and demographics

A retrospective, observational cohort study using data from multiple databases in Colorado was conducted to assess the association of RDV treatment with long-term mortality after COVID-19 hospitalization (N=9760). Included in the analysis were adult patients with both documentation of a positive COVID-19 test between November 2020 and October 2022 and hospitalization within 28 days following the index COVID-19 date. Patients who received outpatient antiviral treatments after their index hospitalization or died during their index hospitalization were excluded from the analysis. Secondary outcomes included rehospitalization or repeat ED visits ≤28 days after being discharged from the hospital.

Table 2. Baseline Demographics and Disease Characteristics (Agarwal et al)²

Key Demographics and Characteristics		RDV (n=4771)	No RDV (n=4989)
Age group, years, n (%)	18–44	1194 (25)	2860 (57.3)
	45–64	1774 (37.2)	980 (19.6)
	≥65	1803 (37.8)	1149 (23)
Female, n (%)		2200 (46.1)	3362 (67.4)
LOS, median (IQR), days		4 (2–7)	2 (1–4)
Maximum level of respiratory support, n (%)	No supplemental O ₂	155 (3.2)	2892 (58)
	Standard O ₂	3238 (67.9)	1709 (34.3)
	HFO/NIV	1083 (22.7)	265 (5.3)
	IMV	295 (6.2)	123 (2.5)

Results

Overall, 1057 patients (10.8%) were rehospitalized, and 1053 patients (10.8%) went to the ED within 28 days after index hospitalization discharge. In an adjusted Cox proportional hazard model, RDV treatment during the index hospitalization was associated with a decreased risk of both rehospitalization and ED visit after discharge (Table 3).

Table 3. Adjusted Cox Proportional Hazard Model for Rehospitalization and ED Visit Within 28 Days of Index Hospitalization Discharge (Agarwal et al)²

Outcome, n (%)	RDV (n=4771)	No RDV (n=4989)	aHR ^a (95% CI)
Rehospitalization within 28 days	536 (11.2)	521 (10.4)	0.77 (0.67–0.89)
ED visit within 28 days after discharge	479 (10)	574 (11.5)	0.79 (0.67–0.92)

^aAdjusted for age, sex, race, ethnicity, insurance status, immunocompromised status, cardiovascular/pulmonary disease, number of other comorbidities, number of vaccinations, pre-hospital mAb/antiviral treatment status, healthcare system, pandemic phase, index hospitalization LOS, and highest level of O₂ intervention.

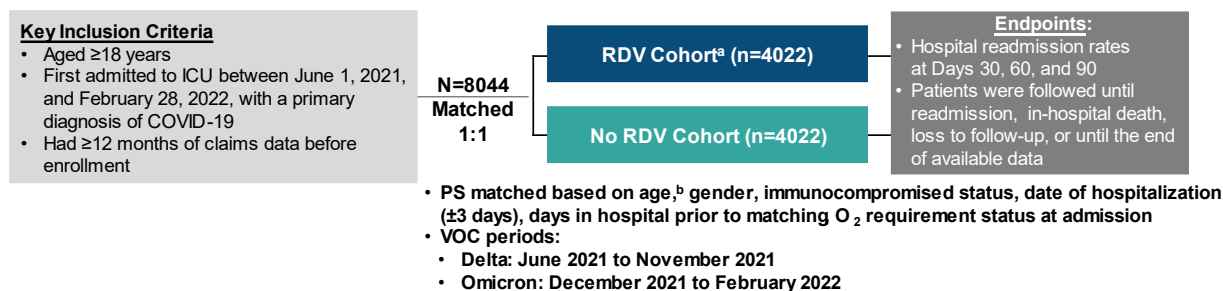
HealthVerity Real-Time Insights and Evidence Database³

Study design

A retrospective, observational, PS-matched study compared rates of all-cause hospital readmission between patients admitted to the ICU who did and did not receive treatment with RDV during their hospitalization and who had a discharge diagnosis of COVID-19. Data were obtained from the US-based HealthVerity Real-Time Insights and Evidence Database and were analyzed across two VOC time periods (Delta and Omicron SARS-CoV-2).

Readmission rates at 30, 60, and 90 days after the index date (date of RDV initiation or corresponding match date) were examined. No baseline demographics were provided.

Figure 4. Retrospective Observational Study Design (Bansode et al)³



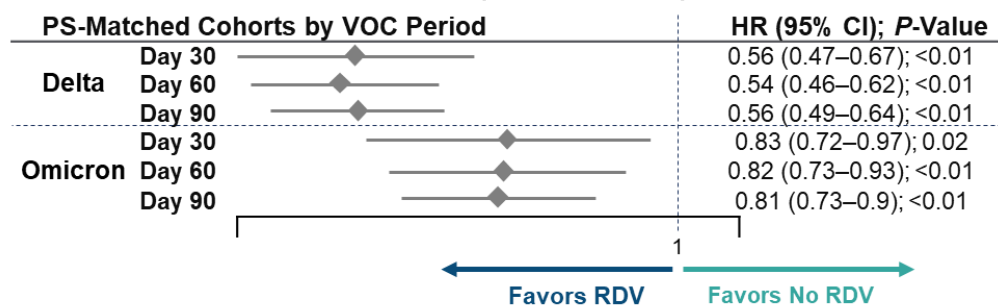
^aReceived ≥1 dose of RDV during hospitalization. Participants in the no RDV cohort were censored at the time of RDV initiation, if applicable.

^bAge ranges: <18, 18–29, 30–39, 40–49, 50–59, 60–74, and ≥75 years.

Results

Readmission rates at each time point were lower in the RDV cohort than in the no RDV cohort. In a Cox proportional hazards model with multivariable adjustment, treatment with RDV was associated with a significantly lower risk of readmission at each time point assessed across both VOC periods (Figure 5).

Figure 5. Risk of Readmission at Days 30, 60, and 90 During the Delta and Omicron VOC Periods (Bansode et al)³



References

1. 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:e230131.
2. Agarwal T, Beaty LE, Carlson NE, et al. Association of remdesivir treatment with long-term mortality after COVID-19 hospitalization. *BMC Infect Dis*. 2025;25(1):1418.
3. Bansode S, Singh PK, Tellis M, et al. A Comprehensive Molecular and Clinical Investigation of Approved Anti-HCV Drugs Repurposing against SARS-CoV-2 Infection: A Glaring Gap between Benchside and Bedside Medicine. *Vaccines (Basel)*. 2023;11(3).
4. Mozaffari E, Chandak A, Gottlieb RL, et al. Remdesivir Reduces All-cause and COVID-19 Related Readmission after Initial Hospitalization [Poster 105]. Paper presented at: The Society for Hospital Medicine (SHM); April 12-15, 2024; San Diego, CA.

Abbreviations

aHR=adjusted hazard ratio
aOR=adjusted odds ratio
CCI=Charlson Comorbidity Index
ECMO=extracorporeal membrane oxygenation
ED=emergency department

HFO=high-flow O₂
ICU=intensive care unit
IMV=invasive mechanical ventilation
LOS=length of stay
NIV=non-invasive ventilation
O₂=oxygen

OR=odds ratio
PINC AI=Premier Inc. Artificial Intelligence
PS=propensity score
RDV=remdesivir
VOC=variants of concern

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Veklury US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 www.askgileadmedical.com

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🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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