GILEAD | Medical Information

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).

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

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 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.[2]

A retrospective, observational cohort study within a network of three hospitals in Rhode Island (N=2062) that evaluated the risk of readmission at Day 30 after the index hospitalization for COVID-19 found that relative to no treatment with RDV, treatment with RDV was associated with a 19% decrease in the risk of readmission at Day 30 (RR, 0.81; 95% CI: 0.59–1.13), and among patients with mild COVID-19 disease, RDV was associated with a 69% decrease in the risk of readmission at Day 30 (RR: 0.31; 95% CI: 0.13–0.75) relative to those who did not receive RDV.[3]

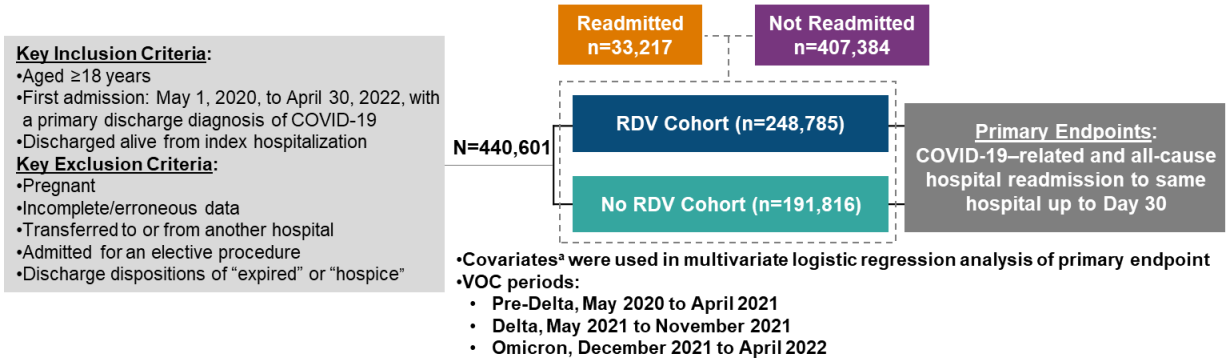
Real-World Studies on Hospital Readmissions Following Use of RDV

PINC AI Healthcare Database

Study design and demographics[1]

A retrospective observational study compared rates of all-cause or COVID-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 O_2, low-flow O_2, HFO/NIV, and IMV/ECMO).

Figure 1. Retrospective Observational Study Design[1]



[a]Covariates included age, receipt of corticosteroids, VOC period, CCI, maximum O_2 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[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	–	–

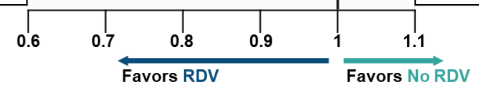
[a]Defined as the highest level of O_2 required during hospitalization.

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 O_2 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 O_2 Requirement During Index Hospitalization[1]

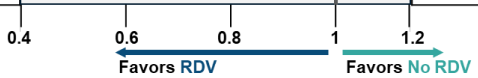
	Unadjusted Analysis		Adjusted Analysis		
	All-Cause Readmission up to Day 30, n/N (%)		Likelihood of All-Cause Readmission by Day 30, aOR (95% CI)	aOR (95% CI)	*P*-Value
	RDV	No RDV			
Overall	**15,780/248,785 (6.3)**	**17,437/191,816 (9.1)**		**0.73 (0.72–0.75)**	**<0.0001**
Pre-Delta	7766/122,560 (6.3)	10,176/109,348 (9.3)		0.69 (0.67–0.71)	<0.0001
Delta	4256/83,178 (5.1)	3466/44,215 (7.8)		0.72 (0.68–0.76)	<0.0001
Omicron	3758/43,047 (8.7)	3795/38,253 (9.9)		0.87 (0.83–0.92)	<0.0001
Maximum O_2 requirement during index hospitalization					
No O_2	4806/73,859 (6.5)	9055/99,030 (9.1)		0.7 (0.67–0.73)	<0.0001
Low-flow O_2	7025/115,923 (6.1)	6181/68,389 (9)		0.73 (0.7–0.76)	<0.0001
HFO/NIV	3379/50,029 (6.8)	1834/19,815 (9.3)		0.82 (0.77–0.87)	<0.0001
IMV/ECMO	570/8974 (6.4)	367/4582 (8)		0.87 (0.76–1.01)	0.0613



Note: ORs were adjusted using the following covariates: age group, use of corticosteroids, VOC period, CCI, maximum O_2 requirement, and ICU stay during hospitalization.

Figure 3. COVID-19–Related Readmissions Up to Day 30: Overall, by VOC Periods, and by Maximum O_2 Requirement During Index Hospitalization[1]

	Unadjusted Analysis		Adjusted Analysis		
	COVID-19–Related Readmission up to Day 30, n/N (%)		Likelihood of COVID-19–Related Readmission by Day 30, aOR (95% CI)	aOR (95% CI)	*P*-Value
	RDV	No RDV			
Overall	**7453/248,785 (3)**	**10,396/191,816 (5.4)**		**0.6 (0.58–0.62)**	**<0.0001**
Pre-Delta	3921/122,560 (3.2)	6656/109,348 (6.1)		0.54 (0.52–0.57)	<0.0001
Delta	2031/83,178 (2.4)	2021/44,215 (4.6)		0.61 (0.57–0.65)	<0.0001
Omicron	1501/43,047 (3.5)	1719/38,253 (4.5)		0.77 (0.72–0.83)	<0.0001
Maximum O_2 requirement during index hospitalization					
No O_2	2555/73,859 (3.5)	5883/99,030 (5.9)		0.55 (0.52–0.57)	<0.0001
Low-flow O_2	3487/115,923 (3)	3630/68,389 (5.3)		0.61 (0.58–0.65)	<0.0001
HFO/NIV	1301/50,029 (2.6)	795/19,815 (4)		0.73 (0.67–0.8)	<0.0001
IMV/ECMO	110/8974 (1.2)	88/4582 (1.9)		0.72 (0.54–0.97)	0.0301



Note: ORs were adjusted using the following covariates: age group, use of corticosteroids, VOC period, CCI, maximum O_2 requirement, and ICU stay during hospitalization.

Follow-up analysis through April 2023[4]

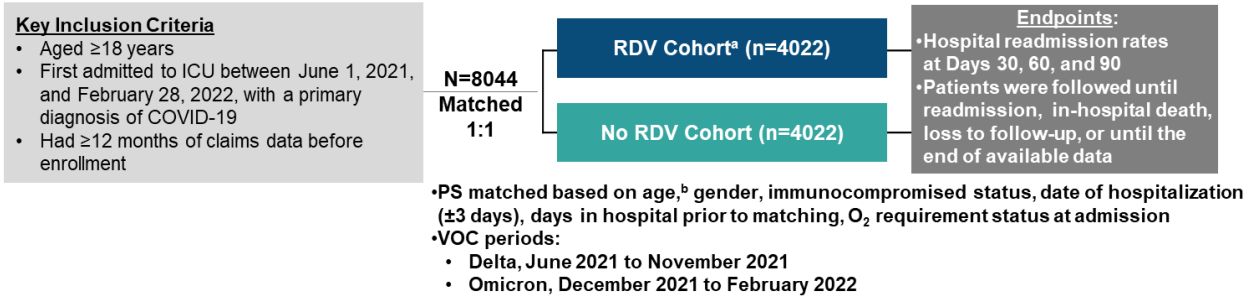
An updated analysis of data through April 2023 included 327,514 patients who received RDV and 262,979 who did not receive RDV. In an unadjusted analysis, and relative to no RDV treatment, patients treated with RDV had a lower all-cause readmission rate (7.7% vs 10.1%) and a lower COVID-19–related readmission 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 O_2 and with any supplemental O_2 requirement.

HealthVerity Real-Time Insights and Evidence Database[2]

Study design and demographics

A retrospective observational 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[2]

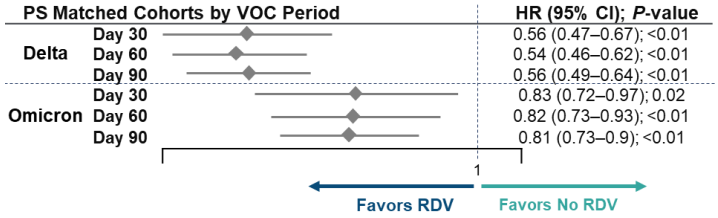


[a]Received ≥1 dose of RDV during hospitalization. Participants in the no RDV cohort were censored at the time of RDV initiation, if applicable.
[b]Age ranges: <18, 18–29, 30–39, 40–49, 50–59, 60–74, and ≥75 years.

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[2]



Retrospective, Multicenter Cohort Study in Rhode Island[3]

Study design and demographics

A retrospective, observational, multicenter cohort study evaluated the association between readmission at Day 30 after the index hospitalization for patients who tested positive for SARS-CoV-2 and treatment with RDV during their stay. Data were obtained from the electronic health records of eligible patients who were admitted to three hospitals in Rhode Island, USA, between April 1, 2020, and December 31, 2020. Patients were followed through postdischarge Day 30 to determine the Day 30 readmission rate and all-cause mortality and the LOS. Socioeconomic (gender, age, race, insurance type, smoking status, and medical history) and clinical data were leveraged in IPTW and IPCW models to address potential confounders of indication and selective survival, respectively. Baseline characteristics were generally similar between groups; however, a greater proportion of patients in the RDV group were older, were male, and required some degree of respiratory support.

Table 2. Select Baseline Demographics and Disease Characteristics[3]

Key Demographics and Characteristics	Overall	RDV	No RDV
Patients/hospitalizations	2062/2279	742/748	1369/1531
Age, mean (SD), years	63.4 (17.9)	64.2 (16.7)	63 (18.4)
Male, %	53.6	57.6	51.6
Most common (>35% in any group) medical conditions, %			
Hypertension/cardiac/diabetes/ pulmonary/current or former tobacco user	62.3/43.8/41.3/ 38.4/35.2	63.5/41.8/42.5/ 40.1/35.8	61.7/44.9/40.7/ 37.6/34.8

Results

Table 3. Treatment Outcomes Overall and by Treatment Cohort[3]

Treatment Outcomes	Overall	RDV	No RDV
Neither readmitted nor deceased at Day 30, %	77.9	79.9	76.9
Readmitted within 30 days, %	10.6	8.3	11.8
Died within 30 days, %	11.5	11.8	11.4

Relative to no treatment with RDV, treatment with RDV was associated with a 19% decrease in the risk of readmission at Day 30, though the difference was not significant; among patients with mild COVID-19 disease, RDV was significantly associated with a 69% decrease in risk of readmission at Day 30 compared with non-receipt of RDV (Table 4).

Table 4. Day 30 Readmission Overall and by COVID-19 Severity[3]

		Overall	RDV	No RDV	Day 30 Readmission,[a] RR (95% CI)
Overall, n		2279	748	1531	0.81 (0.59–1.13)
COVID-19 severity, n	Mild[b]	806	85	721	0.31 (0.13–0.75)
	Moderate[c]	846	359	487	0.77 (0.45–1.32)
	Severe[d]	627	304	323	0.7 (0.38–1.28)

[a]Generalized models used IPCW and IPTW to decrease the impact of confounders that could have affected treatment assignment and survival; additionally, the model controlled for the month of hospital admission and whether the patient had a respiratory rate >30 breaths/minute within the first 24 hours of admission.
[b]Did not require supplemental O_2.
[c]Required 0.5–6 L/minute of maximal O_2 support.
[d]Required ≥6.5 L/min O_2 support (including HFO, NIV, and mechanical ventilation).

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;13(4):e230131.
2. 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). https://www.ncbi.nlm.nih.gov/pubmed/36992099
3. Finn A, Jindal A, Andrea SB, Selvaraj V, Dapaah-Afriyie K. Association of Treatment with Remdesivir and 30-day Hospital Readmissions in Patients Hospitalized with COVID-19. *Am J Med Sci.* 2022;363(5):403-410. https://www.ncbi.nlm.nih.gov/pubmed/35151637
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

aOR=adjusted odds ratio
CCI=Charlson Comorbidity Index
ECMO=extracorporeal membrane oxygenation
HFO=high-flow O_2
HR=hazard ratio
ICU=intensive care unit
IMV=invasive mechanical ventilation
IPCW=inverse probability of censoring weights
IPTW=inverse probability of treatment weights
LOS=length of stay
NIV=non-invasive ventilation
O_2=oxygen
PINC AI=Premier Inc. Artificial Intelligence
PS=propensity score
RDV=remdesivir
RR=relative risk
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

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.