Veklury®
remdesivir 100 MG FOR INJECTION

LEADING THE WAY

A multistudy review of clinical and contemporary real-world outcomes

MAKING THE CASE FOR VEKLURY® TREATMENT IN PATIENTS HOSPITALIZED WITH COVID-19, **NOT REQUIRING SUPPLEMENTAL OXYGEN**

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 within and full Prescribing Information.

COVID-19 poses an ongoing public health concern, especially for patients with risk factors for progression[1,2]

COVID-19 remains a significant cause of mortality and hospitalizations in the United States[3,4]

- The CDC reported **47,251 provisional death counts involving COVID-19 and 9382 involving influenza** in the United States in 2024[3,*]
- In the same year, the CDC reported a **hospitalization rate ~2.5x higher for COVID-19 compared with influenza** (151 vs 65 per 100,000 people)[4,†]

*Deaths with confirmed or presumed COVID-19, pneumonia, or influenza, coded to ICD-10 codes U07.1 or J09-J18.9.

†RESP-NET conducts surveillance for laboratory-confirmed hospitalizations of COVID-19 (COVID-NET), influenza (FluSurv-NET), and RSV (RSV-NET). Rates presented capture cumulative figures for COVID-19 and influenza-associated hospitalizations and were not adjusted for testing practices, which may differ by pathogen, age, race/ethnicity, and other demographic criteria.

Older adults and/or patients with certain comorbidities are at higher risk for severe COVID-19[5]

≥65 years

Age remains the strongest risk factor for severe COVID-19 outcomes[5,6]

People aged ≥65 years accounted for ~63% of COVID-19–associated hospitalizations and ~88% of COVID-19–associated in-hospital deaths.[7,‡]

‡Data from January to August 2023.
Source: CDC; COVID-NET conducts population-based surveillance for laboratory-confirmed COVID-19–associated hospitalizations across 13 US states.

Patients with comorbidities have an increased risk for progression to severe COVID-19, including death.[8]

COVID-19 death risk ratio for select comorbid conditions[8]

Comorbidities	Death Risk Ratio Increase	aRR (95% CI)
Obesity	30%	1.30 (1.27 to 1.33)
Diabetes with complications	26%	1.26 (1.24 to 1.28)
Chronic kidney disease	21%	1.21 (1.19 to 1.24)
COPD and bronchiectasis	18%	1.18 (1.16 to 1.20)
Neurocognitive disorders	18%	1.18 (1.15 to 1.21)
CAD and other heart disease	14%	1.14 (1.12 to 1.16)

COVID-19 death risk ratio increases as the number of underlying conditions increase[8]

Number of Conditions	Death Risk Ratio Increase	aRR (95% CI)
No conditions	1x	Reference
1 condition	1.53x	1.53 (1.41 to 1.67)
2 to 5 conditions	2.55x	2.55 (2.32 to 2.80)
6 to 10 conditions	3.29x	3.29 (2.98 to 3.63)
>10 conditions	3.82x	3.82 (3.45 to 4.23)

Source: CDC; Premier Healthcare Database, Special COVID-19 Release, March 2020–March 2021. US hospital–based data collected from 540,667 adults hospitalized for COVID-19.

aRR=adjusted risk ratio; CAD=coronary atherosclerosis disease; COPD=chronic obstructive pulmonary disease; ICD-10=International Classification of Diseases, 10th Revision.

Comorbidity prevalence is high in patients hospitalized with COVID-19 who do not require supplemental oxygen[9]

Real-world data

A large, real-world, retrospective study analyzed over 120,000 adult patients (≥18 years of age), not requiring supplemental oxygen at baseline.

Prevalence of select comorbidities in patients hospitalized for COVID-19 without supplemental oxygen requirements at baseline

Comorbidities	Study population (N=121,336) n (%)
Obesity	**37,557** (31)
COPD	**27,463** (23)
Cardiovascular disease	**92,834** (77)
Diabetes mellitus	**45,755** (38)
Renal disease	**26,392** (22)
Cancer	**5,253** (4)

Among the real-world study population, multiple conditions were highly prevalent in patients who did not require supplemental oxygen while hospitalized with COVID-19[10]

Of patients hospitalized with COVID-19 not requiring supplemental oxygen at baseline[10]:

89% had **≥1 condition**

52% had **2-3 conditions**

10% had **4-6 conditions**

Source: PINC AI™ Healthcare database, December 2020–April 2022; N=121,336.

COPD=chronic obstructive pulmonary disease.

VEKLURY significantly reduced risk of hospitalization or death in patients not on supplemental oxygen[11,12]

87%

Lower risk of COVID-19–related hospitalization or death from any cause by Day 28

- 0.7% of nonhospitalized patients treated with VEKLURY (n=2/279), compared to 5.3% of patients treated with placebo (n=15/283), had a COVID-19–related hospitalization or death from any cause by Day 28; HR: 0.13 (95% CI, 0.03 to 0.59), *P* = 0.008
- No deaths were reported in either group by Day 28

The safety profiles of VEKLURY and placebo were comparable

- The primary safety endpoint of any adverse event was reported in 42.3% of patients treated with VEKLURY vs 46.3% of patients treated with placebo
- The most common adverse reaction (≥5%) in patients taking VEKLURY was nausea

The PINETREE study (GS-US-540-9012) was a phase 3, randomized, double-blind, placebo-controlled clinical trial in patients who were randomized to receive VEKLURY (n=279) or placebo (n=283) for 3 days. Patients included in the study were **not hospitalized**, had confirmed positive results for SARS-CoV-2 infection, showed symptoms of mild-to-moderate COVID-19 for ≤7 days, and had at least 1 risk factor for progression to hospitalization. The **primary efficacy endpoint** was a composite of COVID-19–related hospitalization (defined as ≥24 hours of acute care) or death from any cause by Day 28. The primary safety endpoint was any adverse event.

Patients who received, required, or were expected to require supplemental oxygen were excluded from the trial

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.

Please see additional Important Safety Information within and full Prescribing Information.

HR=hazard ratio.

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VEKLURY reduced disease progression and recovery time in patients hospitalized for COVID-19[11,13]

In the ACTT-1 overall study population, patients experienced:

5 DAYS SHORTER RECOVERY TIME WITH VEKLURY

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

VEKLURY reduced progression to new oxygen support

10%

Absolute reduction in incidence of new mechanical ventilation or ECMO with VEKLURY vs placebo

13% of hospitalized patients treated with VEKLURY (n=402) vs 23% with placebo (n=364) in patients who did not receive either at baseline (95% CI, -15 to -4)

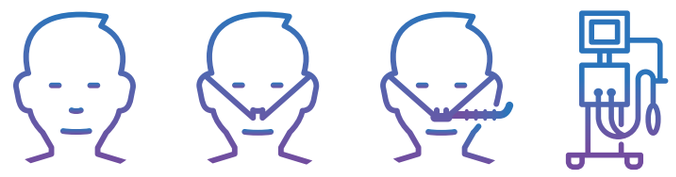
- Disease progression was a secondary endpoint

At baseline in the overall population,

- **138 patients (13%) did not require supplemental oxygen but required ongoing medical care (COVID-19–related or otherwise)**
- 435 patients (41%) required supplemental oxygen
- 193 patients (18.2%) required noninvasive ventilation or high-flow oxygen devices
- 285 patients (26.8%) received invasive mechanical ventilation or ECMO

Adverse reaction frequency was comparable between VEKLURY and placebo—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 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. Patients received VEKLURY (n=541) or placebo (n=521) for up to 10 days. The **primary endpoint** was time to recovery within 29 days after randomization. Recovery was defined as patients who were no longer hospitalized or hospitalized but no longer required ongoing COVID-19 medical care.



VEKLURY is FDA approved for patients hospitalized with COVID-19, irrespective of supplemental oxygen requirement

[§]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)

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 within and full Prescribing Information.

ECMO=extracorporeal membrane oxygenation; HR=hazard ratio.

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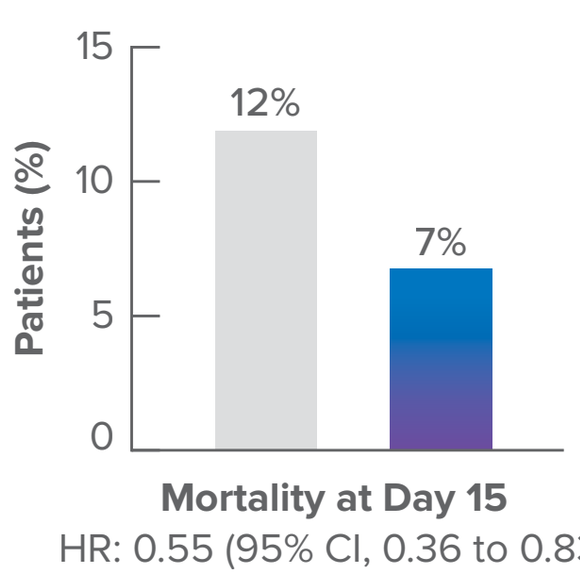
Mortality in the ACTT-1 overall population[11,13]

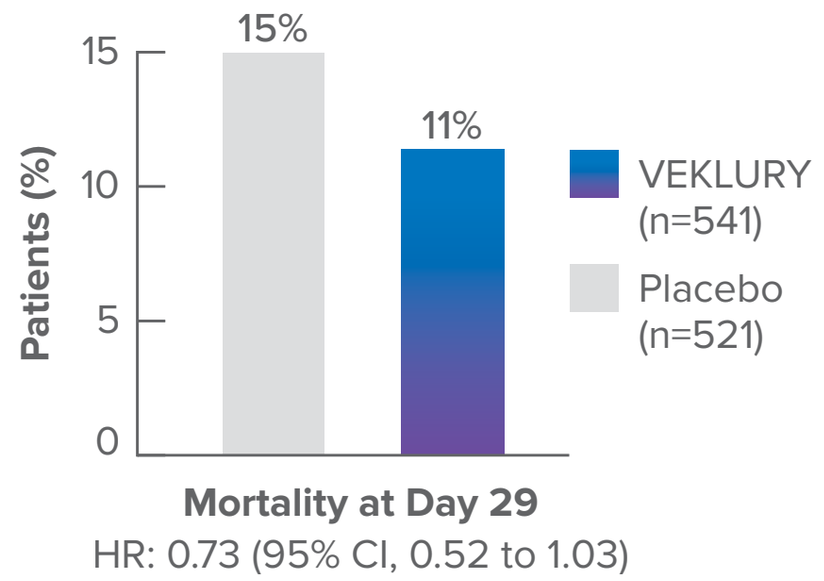
Mortality at Day 29 was a prespecified secondary endpoint

Results in the overall population at Day 29 were not statistically significant.

- The ACTT-1 study was not powered to evaluate a difference in mortality in the overall population



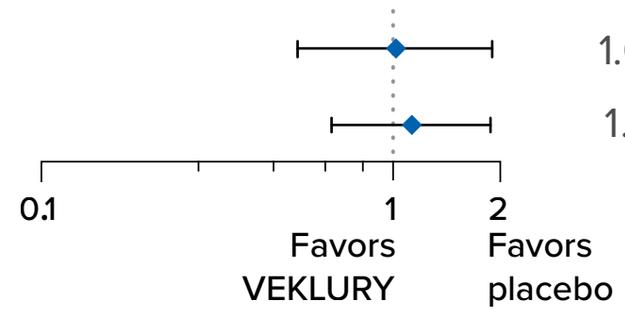
Mortality at Day 15
HR: 0.55 (95% CI, 0.36 to 0.83)



Mortality at Day 29
HR: 0.73 (95% CI, 0.52 to 1.03)

Mortality rates by ordinal scale at Day 29, a post hoc subgroup analysis[13,14]

Entire study (Day 29)	Number of deaths/number of patients: VEKLURY	Placebo	HR (95% CI)
Ordinal score at baseline			
4	3/75	3/63	0.82 (0.17 to 4.07)
5	9/232	25/203	0.30 (0.14 to 0.64)
6	19/95	20/98	1.02 (0.54 to 1.91)
7	28/131	29/154	1.13 (0.67 to 1.89)



VEKLURY reduced mortality rates at Day 29 in patients on low-flow oxygen at baseline by 70% vs placebo. HR: 0.30 (95% CI, 0.14 to 0.64)

- No difference was demonstrated in the other baseline oxygen status subgroups
- There was no adjustment to control for multiple testing in this post hoc analysis

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.

- **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.

Please see additional Important Safety Information within and full Prescribing Information.

HR=hazard ratio.

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Mortality outcomes in the SOLIDARITY trial[15]

VEKLURY reduced mortality in patients on supplemental oxygen in the SOLIDARITY trial

13%

Relative risk reduction in mortality was observed in the combined analysis of patients on low- and high-flow oxygen at baseline vs control arm

- 14.6% with VEKLURY vs 16.3% in the control arm; rate ratio: 0.87 (95% CI, 0.76 to 0.99), *P* = 0.03; n=5,839

- **Mortality in the overall population was 14.5% with VEKLURY vs 15.6% in the control arm**, which was not statistically significant; rate ratio: 0.91 (95% CI, 0.82 to 1.02), *P* = 0.12

The **WHO SOLIDARITY** trial was an open-label, multicenter clinical trial that was conducted in 35 countries and enrolled consenting adults (aged ≥18 years) recently hospitalized with, in the view of their doctor, definite COVID-19. 8275 patients were randomized (1:1) to either receive VEKLURY (n=4146) or to its control (n=4129).[¶] Patients in the VEKLURY arm received a single loading dose of VEKLURY 200 mg IV on Day 1, followed by once-daily maintenance doses of VEKLURY 100 mg IV for up to 9 days unless discharged earlier.

The **primary outcome** was in-hospital mortality, overall, and subdivided by disease. Severity was defined as no oxygen at entry, on oxygen at entry, or already ventilated.[#]

[¶]All patients were to receive the local standard of care, in addition to any study drugs. Participants were randomly allocated in equal proportions between the locally available options, to receive whichever of the 4 study drugs (lopinavir, hydroxychloroquine, IFN-β1a, or VEKLURY) were locally available at that time or no study drug (controls).
[#]The nonventilated supplemental oxygen subgroup comprised the low- and high-flow oxygen subgroups.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration** (cont'd)**:**
  - For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.
  - 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.

Please see additional Important Safety Information within and full Prescribing Information.

IFN-β1a=interferon beta-1a; WHO=World Health Organization.

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Real-world mortality outcomes in patients treated with VEKLURY across oxygen subgroups

A large, real-world, retrospective, comparative effectiveness study examined all-cause in-hospital mortality in adult patients (≥18 years of age) who were treated with VEKLURY vs those not treated with VEKLURY across variant periods (12/2020–4/2022). The study period covered the pre-BA4/5 variant period.[9,16,17]

The **primary outcome** was 14-day and 28-day all-cause in-hospital mortality (defined as a discharge status of "expired" or "hospice").[9,16,17]

- VEKLURY-assigned patients received at least 1 dose of VEKLURY within 2 days of hospitalization[9,16,17,**]
- Analyses performed based on the supplemental oxygen requirements upon admission and by variant period[9,16,17]
- This study was sponsored by Gilead Sciences, Inc.[9,16,17]

Data source[9,16,17]

PINC AI™ Healthcare Database: This US hospital–based, service-level, all-payer (including commercial, Medicare, Medicaid, and other payers) database covered approximately 25% of all US hospitalizations across 48 states.

Study population[17]

- 213,264 patient records with a primary COVID-19 diagnosis were analyzed
  - This included **121,336 patients <u>not</u> requiring supplemental oxygen** upon admission[9]
- 164,791 VEKLURY patients were matched to 48,473 non-VEKLURY patients (equivalent to 164,791 based on 1:1 matching with replacement) using preferential same-hospital matching.[††] Postmatching, groups balanced across baseline supplemental oxygen and variant periods

Key matching factors included:

- Age
- Gender
- Race
- Ethnicity
- Comorbidities
- Hospital characteristics
- Variant period
- Concomitant COVID-19 medications[‡‡]

**Refer to the Dosing and Administration section of the full Prescribing Information for dosage recommendations.

††If unmatched within the same hospital, patients of the same age group, supplemental oxygenation status, and 2- to 3-month blocks of admission month from another hospital of the same bed-size category.

‡‡Other treatments administered at baseline for patients (across both study arms) included anticoagulants, corticosteroids, convalescent plasma, tocilizumab, and baricitinib.

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 additional Important Safety Information within and full Prescribing Information.

PINC AI™ is a trademark of Premier, Inc. (formerly Premier Healthcare Database).

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Real-world mortality outcomes in patients treated with VEKLURY across oxygen subgroups (cont'd)

SELECT POPULATION CHARACTERISTICS

Before matching, compared to non-VEKLURY patients[17]:

- **VEKLURY patients were younger** (46% aged ≥65 years vs 57%)
- **VEKLURY patients had lower rates of:**
  - Cardiovascular disease (74% vs 83%)
  - Diabetes (38% vs 41%)
  - Renal disease (15% vs 30%)
  - Immunocompromised conditions (23% vs 37%)
- **VEKLURY patients had a higher rate of obesity** (40% vs 32%)
- **VEKLURY patients were less likely to have/be on:**
  - NSOc (36% vs 48%)
  - IMV/ECMO (3% vs 4%)

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 or bias. Real-world data should be considered in the context of all available data; results may differ between studies.

Strengths[9,16]

- Large sample size from a multicenter database across variant periods
- Primary diagnosis for hospitalization was COVID-19
- Matching accounted for key factors

Limitations[9,16]

- Potential for residual confounding due to unmeasured variables, including differences in groups that could not be accounted for
- The analysis did not account for the following information that was not in the database: 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

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IMPORTANT SAFETY INFORMATION (cont'd)

Contraindication

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

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ECMO=extracorporeal membrane oxygenation; IMV=invasive mechanical ventilation; NSOc=no supplemental oxygen charges.

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LEADING THE WAY

Real-world study

Patients treated early with VEKLURY had significantly reduced mortality across all oxygen subgroups[9,16]

Mortality reduction at Day 28: VEKLURY (within 2 days of admission) vs matched controls (12/2020 through 04/2022)

Among patients with no supplemental oxygen charges

17%

LOWER MORTALITY RISK

aHR: 0.83 (95% CI, 0.76 to 0.90), $P < 0.001$

n=116,376

Among patients with low-flow oxygen

21%

LOWER MORTALITY RISK

aHR: 0.79 (95% CI, 0.73 to 0.85), $P < 0.0001$

n=135,164

Among patients with high-flow oxygen or NIV

12%

LOWER MORTALITY RISK

aHR: 0.88 (95% CI, 0.82 to 0.93), $P < 0.0001$

n=69,714

Among patients with IMV/ECMO

26%

LOWER MORTALITY RISK

aHR: 0.74 (95% CI, 0.67 to 0.82), $P < 0.0001$

n=8,328

Significantly lower mortality was observed across all supplemental oxygen subgroups in patients who were treated with VEKLURY within 2 days of admission across multiple variant periods vs matched controls who did not receive VEKLURY during hospitalization.

"Evidence of the association between [VEKLURY] use and lower mortality rate from this large observational study may inform clinicians in the management of patients with COVID-19 admitted without hypoxemia."

— Mozaffari E, et al. *Open Forum Infect Dis*. 2024;11(6):ofae202.

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).

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aHR=adjusted hazard ratio; ECMO=extracorporeal membrane oxygenation; IMV=invasive mechanical ventilation; NIV=noninvasive ventilation.

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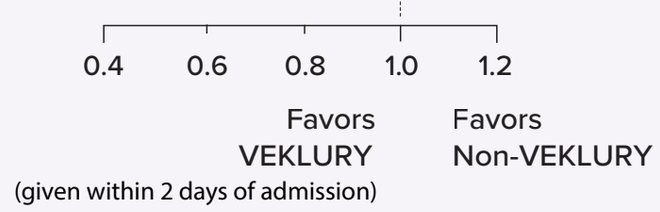
Real-world study

VEKLURY-treated patients had lower mortality risk across multiple variant periods[9,16]

28-day mortality outcomes observed with VEKLURY across baseline supplemental oxygen requirements and variant periods (12/2020 through 4/2022)

	Number of patients	aHR (95% CI)	*P* value
Overall cohort			
No supplemental oxygen charges	116,376	0.83 (0.76 to 0.90)	< 0.001
Low-flow oxygen	135,164	0.79 (0.73 to 0.85)	< 0.0001
High-flow oxygen or NIV	69,714	0.88 (0.82 to 0.93)	< 0.0001
IMV/ECMO	8,328	0.74 (0.67 to 0.82)	< 0.0001
Omicron			
No supplemental oxygen charges	24,154	0.76 (0.68 to 0.86)	< 0.001
Low-flow oxygen	24,616	0.74 (0.66 to 0.82)	< 0.0001
High-flow oxygen or NIV	15,062	0.84 (0.76 to 0.93)	0.0012
IMV/ECMO	2,020	0.71 (0.61 to 0.83)	< 0.0001
Delta			
No supplemental oxygen charges	45,598	0.87 (0.77 to 0.99)	0.03
Low-flow oxygen	57,638	0.81 (0.73 to 0.90)	< 0.0001
High-flow oxygen or NIV	30,332	0.89 (0.82 to 0.97)	0.0072
IMV/ECMO	3,530	0.81 (0.69 to 0.95)	0.0104
Pre-Delta			
No supplemental oxygen charges	46,624	0.83 (0.72 to 0.96)	0.01
Low-flow oxygen	52,910	0.79 (0.70 to 0.90)	0.0002
High-flow oxygen or NIV	24,320	0.88 (0.80 to 0.98)	0.0198
IMV/ECMO	2,778	0.69 (0.58 to 0.82)	< 0.0001



14-day mortality was also statistically significant for all supplemental oxygen requirements across multiple variant periods. In patients treated with VEKLURY, the mortality risk was:

- 25% lower for those who did not receive supplemental oxygen; aHR: 0.75 (95% CI, 0.68 to 0.83), *P* < 0.001; n=116,376
- 28% lower for those on low-flow oxygen; aHR: 0.72 (95% CI, 0.66 to 0.79), *P* < 0.0001; n=135,164
- 17% lower for those on high-flow oxygen or NIV; aHR: 0.83 (95% CI, 0.77 to 0.89), *P* < 0.0001; n=69,714
- 27% lower for those on IMV/ECMO; aHR: 0.73 (95% CI, 0.65 to 0.82), *P* < 0.0001; n=8328

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **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.

Please see additional Important Safety Information within and full Prescribing Information.

aHR=adjusted hazard ratio; ECMO=extracorporeal membrane oxygenation; IMV=invasive mechanical ventilation; NIV=noninvasive ventilation.

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In a real-world study, patients treated with VEKLURY were significantly less likely to be readmitted across variant periods and oxygen subgroups[18]

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 (5/2020–4/2022). The study period 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.

- Data source: PINC AI™ Healthcare Database[18,19]
- Data were examined using multivariate logistic regression[¶¶]
- The study included index patients on room air, low- and high-flow supplemental oxygen, and IMV/ECMO
- VEKLURY-treated patients received at least 1 dose of VEKLURY during index COVID-19 hospitalization[##]
- This study was sponsored by Gilead Sciences, Inc.

Study population

- 440,601 patients from 852 hospitals, with a primary diagnosis of COVID-19 who were discharged alive
  - **39% of the overall population did not require supplemental oxygen** upon admission
- 248,785 VEKLURY patients were compared to 191,816 non-VEKLURY patients
  - Of VEKLURY patients, **30% did not require supplemental oxygen at baseline** compared to 52% of non-VEKLURY patients

The patient population included a broad range of:

- Comorbidities
- Ages
- Supplemental oxygen requirements
- Concomitant medications used[***]

[§§]Defined as a 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 hospitalization for COVID-19.
[¶¶]The model adjusted for age, corticosteroid use, variant period, Charlson Comorbidity Index (CCI), maximum oxygenation requirements, and ICU admission during COVID-19 hospitalization.
[##]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 the aforementioned treatments.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **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.

Dosage and administration

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

Please see additional Important Safety Information within and full Prescribing Information.

ECMO=extracorporeal membrane oxygenation; IMV=invasive mechanical ventilation.

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LEADING THE WAY

In a real-world study, patients treated with VEKLURY were significantly less likely to be readmitted across variant periods and oxygen subgroups[18] (cont'd)

SELECT 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
- **More likely to have received some level of supplemental oxygen support (any supplemental oxygen support, 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 or bias. Real-world data should be considered in the context of all available data; results may differ 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

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.
  - 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.

Please see additional Important Safety Information within and full Prescribing Information.

CCI=Charlson Comorbidity Index; NSOc=no supplemental oxygen charges.

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Real-world study

Patients treated with VEKLURY who did not require supplemental oxygen showed the greatest reduction in readmission rates[18]

Among patients with no supplemental oxygen charges,

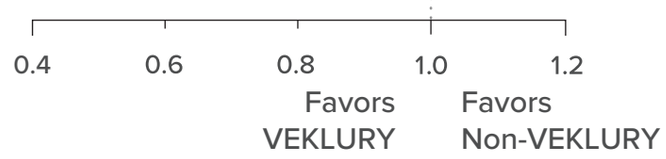
45% ↓

Reduced likelihood of 30-day **COVID-19–related readmission** was observed with VEKLURY

- aOR: 0.55 (95% CI, 0.52 to 0.57), *P* < 0.0001

Statistically significant reduction of 30-day COVID-19–related readmission with VEKLURY was consistently observed across all supplemental oxygen subgroups (5/2020 through 4/2022)

	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
Maximum oxygenation in index hospitalization					
No supplemental oxygen charges	2,555/73,859	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



In the overall population,

40% ↓

Reduced likelihood of **COVID-19–related readmission** within 30 days 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

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **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.

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.

Please see additional Important Safety Information within and full Prescribing Information.

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

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Real-world study

Patients treated with VEKLURY who did not require supplemental oxygen showed the greatest reduction in readmission rates[18] (cont'd)

Among patients with no supplemental oxygen charges,

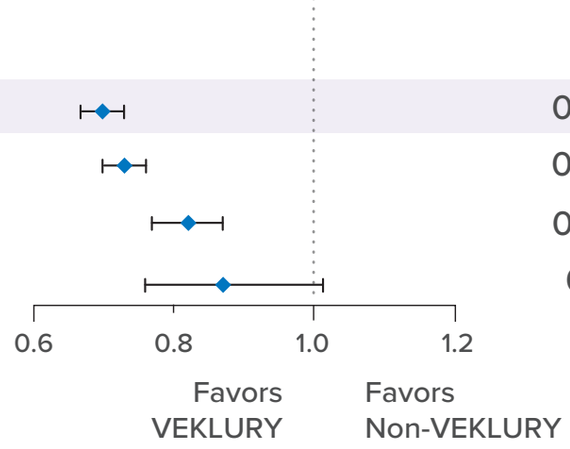
30% ↓

Reduced likelihood of 30-day **all-cause readmission** was observed with VEKLURY

- aOR: 0.70 (95% CI, 0.67 to 0.73), $P < 0.0001$

30-day all-cause readmission with VEKLURY across all baseline supplemental oxygen requirements (05/2020 through 04/2022)

	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
Maximum oxygenation in index hospitalization					
No supplemental oxygen charges	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



In the overall population,

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
- **A statistically significant reduction in the likelihood of 30-day all-cause readmission was observed for all supplemental oxygen levels,** except for patients in the IMV/ECMO group, which did not meet statistical significance due to low sample size in this group[19]

"These findings indicate that the clinical benefit of [VEKLURY] may extend beyond the COVID-19 hospitalization."

— Mozaffari E, et al. *J Comp Eff Res*. 2024;13(4):e230131.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation (cont'd)

- **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 additional Important Safety Information within and full Prescribing Information.

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

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#1 PRESCRIBED ANTIVIRAL

FOR PATIENTS HOSPITALIZED WITH COVID-19[20]

Premier, Inc., and HealthVerity, Inc.; 08/2023 to 09/2024.

THE ONLY NIH RECOMMENDED COVID-19 TREATMENT OPTION

included for adult patients hospitalized for COVID-19[21]

- Not requiring supplemental O_2 and
- Requiring low- or high-flow O_2

Start VEKLURY early in your patients hospitalized with COVID-19, regardless of supplemental oxygen status.

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.

EXPLORE MORE VEKLURY CLINICAL DATA

Please see additional Important Safety Information within and full Prescribing Information.

References: 1. Auwaerter PG. Coronavirus COVID-19 (SARS-CoV-2). Johns Hopkins Medicine POC-IT Guides. Updated October 30, 2024. Accessed March 13, 2025. https://www.hopkinsguides.com/hopkins/view/Johns_Hopkins_ABX_Guide/540747/all/Coronavirus_COVID_19_SARS_CoV_2_ **2.** US Department of Health and Human Services. COVID-19 public health emergency. Reviewed December 15, 2023. Accessed March 13, 2025. https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html **3.** Centers for Disease Control and Prevention. Deaths by week and state. Provisional death counts for COVID-19. Reviewed February 6, 2025. Accessed March 13, 2025. https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm#print **4.** Centers for Disease Control and Prevention. Respiratory Virus Hospitalization Surveillance Network (RESP-NET). Reviewed October 10, 2024. Accessed March 13, 2025. https://www.cdc.gov/resp-net/dashboard/ **5.** Centers for Disease Control and Prevention. Underlying conditions and the higher risk for severe COVID-19. Updated February 6, 2025. Accessed March 13, 2025. https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html?CDC_AAref_Val=https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html **6.** Centers for Disease Control and Prevention. Deaths by select demographic and geographic characteristics. Reviewed September 27, 2023 (archived document). Accessed March 13, 2025. https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm **7.** Taylor CA, Patel K, Patton ME, et al. COVID-19–associated hospitalizations among U.S. adults aged ≥65 years — COVID-NET, 13 states, January–August 2023. *MMWR Morb Mortal Wkly Rep*. 2023;72(40):1089-1094. Reviewed October 18, 2023. Accessed March 13, 2025. https://www.cdc.gov/mmwr/volumes/72/wr/mm7240a3.htm **8.** Kompaniyets L, Pennington AF, Goodman AB, et al. Underlying medical conditions and severe illness among 540,667 adults hospitalized with COVID-19, March 2020–March 2021. *Prev Chronic Dis*. 2021;18:E66. doi:10.5888/pcd18.210123 **9.** Mozaffari E, Chandak A, Chima-Melton C, et al. Remdesivir is associated with reduced mortality in patients hospitalized for COVID-19 not requiring supplemental oxygen. *Open Forum Infect Dis*. 2024;11(6):ofae202. doi.org/10.1093/ofid/ofae202 **10.** Data on file; December 2020 to April 2022. Gilead Sciences, Inc. **11.** VEKLURY. Prescribing Information. Gilead Sciences, Inc.; 2025. **12.** Gottlieb RL, Vaca CE, Paredes R, et al; GS-US-540-9012 (PINETREE) Investigators. Early remdesivir to prevent progression to severe COVID-19 in outpatients. *N Engl J Med*. 2022;386(4):305-315. doi:10.1056/NEJMoa2116846 **13.** 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 **14.** Beigel JH, Tomashek KM, Dodd LE, et al; ACTT-1 Study Group Members. Remdesivir for the treatment of COVID-19 — final report. Supplementary appendix. *N Engl J Med*. 2020;383(19):1813-1826. Accessed March 13, 2025. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2007764/suppl_file/nejmoa2007764_appendix.pdf **15.** WHO Solidarity Trial Consortium. Remdesivir and three other drugs for hospitalised patients with COVID-19: final results of the WHO Solidarity randomised trial and updated meta-analyses. *Lancet*. 2022;399(10339):1941-1953. doi:10.1016/S0140-6736(22)00519-0 **16.** Mozaffari E, Chandak A, Gottlieb RL, et al. Remdesivir is associated with reduced mortality in COVID-19 patients requiring supplemental oxygen including invasive mechanical ventilation across SARS-CoV-2 variants. *Open Forum Infect Dis*. 2023;10(10):1-12. doi:10.1093/ofid/ofad482 **17.** Mozaffari E, Chandak A, Gottlieb RL, et al. Remdesivir reduces mortality in hospitalized COVID-19 patients across variant eras. Poster presented at: 30th Conference on Retroviruses and Opportunistic Infections; February 19-22, 2023; Seattle, WA; poster 556. **18.** 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 **19.** 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. **20.** Data on file; August 2023 to September 2024. Gilead Sciences, Inc. **21.** National Institutes of Health. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. Updated February 29, 2024. Accessed March 13, 2025. https://www.ncbi.nlm.nih.gov/books/NBK570371/pdf/Bookshelf_NBK570371.pdf

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