INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg) with positive results of SARS-CoV-2 viral testing, 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 full Prescribing Information for VEKLURY.
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### References

## 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).
About VEKLURY

What is VEKLURY?

VEKLURY is an antiviral medication that directly inhibits viral replication of SARS-CoV-2. As a SARS-CoV-2 nucleotide analog, VEKLURY acts inside the cell to inhibit the viral RNA-dependent RNA polymerase (RdRp), which is essential for viral replication.1,2

Mechanism of action

1. VEKLURY is a prodrug that distributes into cells where it is metabolized into the pharmacologically active remdesivir triphosphate (RDV-TP).1,2

2. RDV-TP acts as an analog of ATP and competes with it for incorporation into nascent SARS-CoV-2 viral RNA. This results in delayed chain termination (position i+3) and disruption of viral replication.1,2

3. At higher nucleotide concentrations, RDV-TP can also inhibit SARS-CoV-2 RNA synthesis after it has been incorporated into the viral RNA template as a result of read-through by the viral polymerase.1,2

4. The presence of the remdesivir nucleotide in the viral RNA template compromises the ability of the complementary natural nucleotide to be incorporated, thereby inhibiting viral RNA synthesis.1,2

Take a closer look at the mechanism of action video for VEKLURY.

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 full Prescribing Information for VEKLURY.
Does VEKLURY retain antiviral activity against SARS-CoV-2 variants?

To date, known novel virus variants show mutations at different locations in the SARS-CoV-2 spike protein, which is on the outer surface of the virus and can cause decreased affinity of the anti–SARS-CoV-2 antibodies.3-5

No known SARS-CoV-2 variants have significantly altered the viral RNA polymerase.6,7

The antiviral activity of VEKLURY has been tested in vitro against clinical isolates of SARS-CoV-2 variants, including Alpha, Beta, Gamma, Delta, Epsilon, Kappa, Lambda, Iota, Zeta, and Omicron. These laboratory findings demonstrated that the antiviral activity of VEKLURY against these variants is not reduced.1,6

**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.

**Drug interactions**

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

Please see full Prescribing Information for VEKLURY.
What study supports the use of VEKLURY in the outpatient setting?

PINETREE Study (GS-US-540-9012)\(^1,8\)

PINETREE was a phase 3, randomized, double-blind, placebo-controlled clinical trial in patients who 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.

Risk factors included age ≥60 years, obesity (BMI ≥30 kg/m\(^2\)), chronic lung disease, hypertension, cardiovascular or cerebrovascular disease, diabetes mellitus, immunocompromised state, chronic mild or moderate kidney disease, chronic liver disease, current cancer, and sickle cell disease.

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

Primary endpoints
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.

IMPORTANT SAFETY INFORMATION (cont’d)

Dosage and administration

- **Dosage:**
  - For adults and pediatric patients 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.
  - For pediatric patients ≥28 days old and weighing ≥3 kg to <40 kg: 5 mg/kg on Day 1, followed by once-daily maintenance doses of 2.5 mg/kg from Day 2, administered only via intravenous infusion.
What study supports the use of VEKLURY in the outpatient setting? (cont’d)

**Baseline characteristics**

Demographic and baseline clinical characteristics were balanced between the two groups.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>VEKLURY (n=279)</th>
<th>Placebo (n=283)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD, y</td>
<td>50±15</td>
<td>51±15</td>
</tr>
<tr>
<td>Age, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥60 y</td>
<td>83 (29.7)</td>
<td>87 (30.7)</td>
</tr>
<tr>
<td>&lt;18 y</td>
<td>3 (1.1)</td>
<td>5 (1.8)</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>131 (47.0)</td>
<td>138 (48.8)</td>
</tr>
<tr>
<td>Residence in skilled nursing facility, n (%)</td>
<td>8 (2.9)</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>Median duration of symptoms before first infusion (IQR), days</td>
<td>5 (3-6)</td>
<td>5 (4-6)</td>
</tr>
<tr>
<td>Median time since RT-PCR confirmation of SARS-CoV-2 (IQR), days</td>
<td>2 (1-3)</td>
<td>3 (1-4)</td>
</tr>
<tr>
<td>Race or ethnic group, n (%)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>228 (81.7)</td>
<td>224 (79.2)</td>
</tr>
<tr>
<td>Black</td>
<td>20 (7.2)</td>
<td>22 (7.8)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>15 (5.4)</td>
<td>21 (7.4)</td>
</tr>
<tr>
<td>Asian, Native Hawaiian, or Pacific Islander</td>
<td>7 (2.5)</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>Hispanic or Latinx</td>
<td>123 (44.1)</td>
<td>112 (39.6)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (1.1)</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Body mass index, mean ± SD, kg/m²</td>
<td>31.2±6.7</td>
<td>30.8±5.8</td>
</tr>
<tr>
<td>Coexisting conditions, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>173 (62.0)</td>
<td>173 (61.1)</td>
</tr>
<tr>
<td>Obesity</td>
<td>154 (55.2)</td>
<td>156 (55.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>138 (49.5)</td>
<td>130 (45.9)</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>67 (24.0)</td>
<td>68 (24.0)</td>
</tr>
<tr>
<td>Current cancer</td>
<td>12 (4.3)</td>
<td>18 (6.4)</td>
</tr>
<tr>
<td>Cardiovascular or cerebrovascular disease</td>
<td>20 (7.2)</td>
<td>24 (8.5)</td>
</tr>
<tr>
<td>Immune compromise</td>
<td>14 (5.0)</td>
<td>9 (3.2)</td>
</tr>
<tr>
<td>Chronic kidney disease, mild or moderate</td>
<td>7 (2.5)</td>
<td>11 (3.9)</td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td>1 (0.4)</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

*Race and ethnic group were reported by the patients. Patients could have had more than 1 race or ethnic group.

IQR=interquartile range; RT-PCR=reverse transcription–polymerase chain reaction.

**IMPORTANT SAFETY INFORMATION** (cont’d)

**Dosage and administration** (cont’d)

- **Treatment duration:**
  - For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.

*Please see full Prescribing Information for VEKLURY.*
What study supports the use of VEKLURY in the outpatient setting? (cont’d)

VEKLURY reduced risk of progression to severe COVID-19\(^1,8\)

87% lower risk of COVID-19–related hospitalization or death from any cause by Day 28 compared with placebo

- 0.7% of patients treated with VEKLURY compared to 5.3% of patients treated with placebo had a COVID-19–related hospitalization or death from any cause by Day 28; hazard ratio: 0.13, p=0.008
- No deaths were reported in either group by Day 28

The safety profiles of VEKLURY and placebo were comparable\(^1,8\)
- The most common adverse reaction (≥5%) in patients taking VEKLURY was nausea

“Remdesivir is another important option for outpatients with COVID-19.”\(^8\)


Based on the PINETREE Study, the National Institutes of Health (NIH) added VEKLURY to the COVID-19 Treatment Guidelines as a therapeutic option for patients with mild-to-moderate COVID-19 who are not hospitalized but are at risk of disease progression, including hospitalization or death.\(^9\)

Please see the NIH Guidelines for more information on Therapeutic Management of Nonhospitalized Adults With COVID-19.

IMPORTANT SAFETY INFORMATION (cont’d)

Dosage and administration (cont’d)
- Treatment duration: (cont’d)
  - 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 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.

Please see full Prescribing Information for VEKLURY.
Considerations for treatment with VEKLURY

Who is considered at high risk for disease progression?

In the PINETREE Study, high risk was defined as being 12 years of age or older and having at least 1 risk factor associated with progression to hospitalization or death, as follows:

- All patients 60 years of age or older were considered at high risk
- Hypertension
- Chronic lung disease
- Cardiovascular or cerebrovascular disease
- Diabetes mellitus
- Obesity (BMI ≥30 kg/m²)
- Immunocompromised state
- Chronic mild or moderate kidney disease
- Chronic liver disease
- Current cancer
- Sickle cell disease

IMPORTANT SAFETY INFORMATION (cont’d)

Dosage and administration (cont’d)

- **Testing prior to and during treatment:** Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
What should be considered before prescribing VEKLURY?

A center planning to administer VEKLURY in the outpatient setting should consider multiple factors before prescribing VEKLURY, including⁴:

<table>
<thead>
<tr>
<th>For prescribing:</th>
<th>Clinicians should be familiar with the contents of the VEKLURY Prescribing Information. Please see full Prescribing Information for VEKLURY.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements for ordering:</td>
<td>Qualified nonhospital, outpatient facilities are those that have previously administered monoclonal antibodies or completed a certification through AmerisourceBergen Specialty Division.</td>
</tr>
<tr>
<td>Laboratory testing:</td>
<td>Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.</td>
</tr>
<tr>
<td>IV infusion:</td>
<td>The center should have the ability to administer VEKLURY IV infusion for 3 consecutive days, have a designated location for infusion and postinfusion patient monitoring, and have appropriate clinical staffing.</td>
</tr>
<tr>
<td>Adverse events management:</td>
<td>The center should be able to manage any adverse events or reactions and provide additional medical care during or after the infusion, as needed.</td>
</tr>
</tbody>
</table>

IMPORTANT SAFETY INFORMATION (cont’d)

Dosage and administration (cont’d)

• Renal impairment: VEKLURY is not recommended in individuals with eGFR <30 mL/min.
Administration in the outpatient setting

What is the recommended dosage and total treatment duration?

**Recommended dosage**

The recommended dosage for adults and pediatric patients weighing at least 40 kg is a single loading dose of VEKLURY 200 mg on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg from Day 2.

For patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg

For patients who are NOT hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death

Once-daily maintenance dose of 2.5 mg/kg IV

Loading dose of 5 mg/kg IV

Once-daily maintenance dose of 2.5 mg/kg IV

Recommended total treatment duration

For patients who are 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 (cont’d)**

**Dosage and administration (cont’d)**

- **Dose preparation and administration:**
  - There are two different formulations of VEKLURY: VEKLURY for injection (supplied as 100 mg lyophilized powder in vial), the only approved dosage form of VEKLURY for pediatric patients weighing 3 kg to <40 kg; and VEKLURY injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial). See full Prescribing Information.
  - Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.
How long should infusions take, and for how long should patients be monitored?

The standard infusion time is 30–120 minutes.¹

Monitor patients during infusion and observe patients for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate.¹

If signs and symptoms of a clinically significant hypersensitivity reaction occur, immediately discontinue administration of VEKLURY and initiate appropriate treatment.¹

The use of VEKLURY is contraindicated in patients with known hypersensitivity to VEKLURY or any components of the product.¹

How do I administer VEKLURY?

VEKLURY may be administered only in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system, as necessary.¹

Administer VEKLURY for the treatment of COVID-19 in adults and pediatric patients who are 28 days of age and older and weigh at least 3 kg by IV infusion only. Do not administer by any other route.¹

VEKLURY for injection, 100 mg lyophilized powder, must be reconstituted with 19 mL Sterile Water for Injection prior to diluting with 0.9% sodium chloride.¹

Carefully follow the product-specific preparation instructions in the Prescribing Information for VEKLURY or visit vekluryhcp.com.

IMPORTANT SAFETY INFORMATION (cont’d)

Pregnancy and lactation

• Pregnancy: A pregnancy registry has been established. There are insufficient human data on the use of VEKLURY during pregnancy. COVID-19 is associated with adverse maternal and fetal outcomes, including preeclampsia, eclampsia, preterm birth, premature rupture of membranes, venous thromboembolic disease, and fetal death.

• 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.
Ordering and access information

How can I order VEKLURY?

Hospital ordering process
Hospitals can place orders with any of the following distributors by calling directly:

- AmerisourceBergen Specialty Distribution, 1-800-746-6273
- Cardinal Specialty, 1-855-855-0708
- McKesson Plasma, 1-877-625-2566

Nonhospital ordering process
Nonhospitals can contact AmerisourceBergen Specialty Distribution by calling 1-800-746-6273 or emailing C19therapies@AmerisourceBergen.com for more information.

What is the HCPCS code for VEKLURY in the outpatient setting?

On January 7, 2022, the Centers for Medicare & Medicaid Services assigned a permanent HCPCS code, J0248, for VEKLURY in the outpatient setting to help facilitate payment and simplify claims documentation and processing. This code is effective for dates of service on or after December 23, 2021.10

Effective April 1, 2022, the VEKLURY HCPCS code, J0248, has been assigned a pass-through status indicator under the hospital Outpatient Prospective Payment System.11

For more information, please see Coding and Reimbursement Information.
Does VEKLURY have a co-pay coupon program for commercially insured patients?

Commercially insured patients may be eligible for the Gilead Advancing Access® co-pay program for VEKLURY. Restrictions apply. To enroll, patients should call the Advancing Access program at 1-800-226-2056. Phone lines are open M–F, 9 AM–8 PM ET. Voicemails may be left, and a program associate will return calls within the next business day.

Whom do I contact if I have additional questions?

Clinical inquiries may be directed to Gilead Medical Information at 1-866-633-4474. Phone lines are open to speak to a live agent M–F, 5 AM–6 PM PT.

For inquiries about access and coverage, please call the Advancing Access program at 1-800-226-2056 (Option 4), M–F, 9 AM–8 PM ET.

An Advancing Access program specialist is available for further assistance; you can also leave a confidential message any time and day of the week.

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• 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.
References


Please see Important Safety Information within and full Prescribing Information. For more information, visit vekluryhcp.com.