VEKLURY® (remdesivir) Coding and Reimbursement Information

INDICATION

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

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

IMPORTANT SAFETY INFORMATION

Contraindication

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

Please see additional Important Safety Information throughout and click to see full Prescribing Information for VEKLURY.

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Disclaimer: Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. This resource is not intended to be legal advice or a substitute for a provider's independent professional judgement.

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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NDC and ICD-10 codes

NDC[1]	10-digit code	11-digit code
VEKLURY® (remdesivir) 100 mg for injection, lyophilized powder	61958-2901-2	61958-2901-**0**2

Payer requirements regarding the use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference. Please consult with the payer to understand specific billing requirements.

The ICD-10-CM diagnostic code[2]

Code	Description
U07.1	For COVID-19 discharges on or after April 1, 2020

ICD-10-PCS codes for VEKLURY[3]

Code	Description
XW033E5	Introduction of remdesivir anti-infective into *peripheral* vein, percutaneous approach, new technology group 5
XW043E5	Introduction of remdesivir anti-infective into *central* vein, percutaneous approach, new technology group 5

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 throughout and click to see full Prescribing Information for VEKLURY.

ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification; NDC = National Drug Code; PCS = Procedure Coding System.

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Pass-through status and HCPCS code

Medicare pass-through status

- In March 2022, VEKLURY received Medicare transitional pass-through status under the hospital Outpatient Prospective Payment System (OPPS).[4]
- Transitional pass-through payments provide additional payment for new drugs and biologicals that met eligibility criteria for a period of at least two years but not more than three years while Centers for Medicare & Medicaid Services (CMS) gathers additional data on the cost of those items. The intent of pass-through payments is to help facilitate patient access to technologies that are too new to be well represented in the data that CMS uses to set OPPS payment rates.[5]

Effective April 1, 2022, HCPCS code J0248 (injection, remdesivir, 1 mg) was assigned a pass-through drug status indicator under the hospital OPPS.[6]

HCPCS code[7]

Code	Description	Note
J0248	Long: Injection, remdesivir, 1 mg Short: Injection, remdesivir, 1 mg	CMS assigned the HCPCS code J0248 for VEKLURY® antiviral medication when administered in an outpatient setting. This code is available for all payers and is effective for dates of service on or after December 23, 2021.

HCPCS coding requirements will vary by payer, setting of care, and date of service. Please verify patient-specific insurance benefits to confirm specific coding and billing guidelines for VEKLURY.

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.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for VEKLURY.

HCPCS = Healthcare Common Procedure Coding System.

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CPT codes

Code	Description	Code	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	**96367**	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	**96368**	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)

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.
  - 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.

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CPT = Current Procedural Terminology.

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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.
- **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 throughout and click to see full Prescribing Information for VEKLURY.

ADVANCING ACCESS®

For more information about reimbursement, billing, and coding for VEKLURY, please contact GILEAD Advancing Access at **1-800-226-2056** (Option 4) M-F, 9 AM-8 PM ET.

For additional support resources, visit vekluryhcp.com/resources

References: 1. VEKLURY. Prescribing Information. Gilead Sciences, Inc.; 2025. **2.** AAPC. COVID-19: physician coding and reporting guidance. January 9, 2025. Accessed February 4, 2025. https://www.aapc.com/resources/covid-19 **3.** Centers for Medicare & Medicaid Services. New COVID-19 Treatments Add-On Payment (NCTAP). September 10, 2024. Accessed February 4, 2025. https://www.cms.gov/medicare/payment/covid-19-vaccine-toolkit/new-covid-19-treatments-add-payment-nctap **4.** Data on file. Gilead Sciences, Inc. **5.** Medpac. Report to Congress: Medicare and the health care delivery system. June 2020. Accessed February 4, 2025. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch6_reporttocongress_sec.pdf **6.** Centers for Medicare & Medicaid Services. CMS Manual System. Pub 100-04 Medicare Claims Processing, Transmittal 11305. March 24, 2022. Accessed April 15, 2024. https://www.cms.gov/files/document/r11305cp.pdf **7.** Centers for Medicare & Medicaid Services. MLN Connects Newsletter. COVID-19: New HCPCS Code for Remdesivir Antiviral Medication. Updated January 7, 2022. Accessed April 15, 2024. https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2022-01-07-mlnc-se

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