Remdesivir (Veklury) for Outpatient Treatment of COVID-19

February 24, 2022

Effective for dates of service beginning January 21, 2022, the Department of Health Care Services (DHCS) will reimburse Remdesivir (Veklury) as a pharmacy benefit when dispensed for use in nonhospitalized patients in accordance with Food and Drug Administration (FDA) approval or Emergency Use Authorization (EUA).

On January 21, 2022, the FDA expanded the use of Veklury to outpatient settings in certain nonhospitalized pediatric and adult patients who have tested positive for SARS-CoV-2, who have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. These patients can now receive treatments outside of a traditional inpatient setting, including skilled nursing facilities, home healthcare settings, and outpatient facilities such as infusion centers. Based on these developments, DHCS is adding Veklury as a pharmacy benefit.

Veklury inhibits RNA-dependent RNA polymerase, thereby preventing viral replication. It has been approved by the FDA for the treatment of COVID-19 in hospitalized and nonhospitalized adult and pediatric patients 12 years and older and weighing at least 40 kg. Additionally, it is available through an EUA for the treatment of COVID-19 in hospitalized and nonhospitalized pediatric patients weighing 3.5 kg to less than 40 kg or under the age of 12 and weighing at least 3.5 kg. Treatment duration for nonhospitalized patients is 3 days and is initiated as soon as possible after diagnosis of COVID-19, usually within 7 days of symptom onset.

Veklury should be administered in a hospital or healthcare setting where there's immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and with the ability to activate the emergency medical system (EMS) if necessary.

Providers should note that claims would not be separately reimbursed for Federally Qualified Health Centers (FQHCs) that include pharmacy costs in their Prospective Payment System

(PPS). For FQHCs that carve out pharmacy benefits, claims would be billed under their pharmacy reimbursement.

Important Billing Instructions:

- DHCS will reimburse Veklury for the treatment of COVID-19 when administered in accordance with FDA approval or EUA.
- DHCS will reimburse the drug ingredient cost at the Medi-Cal rate.
- DHCS is also reimbursing the professional dispensing fee based on a pharmacy's total (Medicaid and non-Medicaid) annual prescription volume from the previous year as follows:
  - Less than 90,000 claims equal $13.20.
  - 90,000 or more claims equal $10.05.
  - All claims should be submitted to Medi-Cal Rx for processing.
  - Prior authorization is required to ensure that patient selection is in accordance with FDA requirements, based on the following criteria:
    - Patient meets FDA requirements for age and weight.
    - Patient has a positive result of direct SARS-CoV-2 viral testing.
  - Veklury will be administered in settings where severe hypersensitivity reactions, such as anaphylaxis, can be managed and emergency services activated such as skilled nursing facilities, home healthcare settings and outpatient facilities such as infusion centers.
  - The treatment course is being initiated within 7 days of symptom onset.
  - Must comply with the following testing before initiating and during treatment with Veklury:
    - Renal function tests:
      - Determine estimated glomerular filtration rate (eGFR) before starting Veklury and monitor while receiving Veklury.
      - Monitor serum creatinine and creatinine clearance (CrCl).
      - Should not be administered if eGFR is < 30 mL per minute.

  - Patients > 28 days old must have an estimated (eGFR) determined and full-term neonate (≥ 7 days to ≤ 28 days old) must also have serum creatinine determined before treatment initiation and during treatment as clinically appropriate.
  - Should not be administered if eGFR is less than 30 mL per minute in pediatric patients (> 28 days old).
  - Should not be administered in full-term neonates (≥ 7 days to ≤ 28 days old) with serum creatinine ≥ 1 mg/dL.
- Monitor for signs and symptoms of infusion reactions.
- Hepatic function tests:
  - Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, alkaline phosphatase.
  - Avoid use if ALT ≥ 10 times the Upper Limit of Normal (ULN).
  - Discontinue use if ALT elevation and signs or symptoms of liver inflammation.
- Hematology:
  - Determine prothrombin time and monitor serum chemistries before starting Veklury and monitor while receiving Veklury.
    - Veklury is restricted to a maximum of 3 days' supply per dispensing. A prior authorization is required to exceed this with a justification for longer treatment duration.

Pharmacy Providers may bill for the dispensing of Veklury NDCs using NCPDP D.0 claims, web, batch, and paper claims.

NDC	Label Name	Generic Name	Description	PA Required?	Max Quantity
61958290102	Veklury	Remdesivir	100 mg single dose vial, lyophilized powder	Yes	4 vials
61958290202*	Veklury	Remdesivir	100 mg/20 mL	Yes	4 vials
61958290101	Remdesivir (EUA)	Remdesivir	100 mg single dose vial, lyophilized powder	Yes	4 vials
61958290201	Remdesivir (EUA)	Remdesivir	100 mg/20 ml	Yes	4 vials

* When available

For population of claim form fields other than those identified in this guidance, please review the *Medi-Cal Rx Provider Manual*.

Any concerns regarding delay in reimbursement should not cause providers to decline dispensing Veklury to patients.

Providers with questions should contact Medi-Cal Rx at 1-800-977-2273. Customer Service Representatives are available 24 hours a day, 7 days a week, 365 days per year.

For more information on services covered by Medi-Cal Rx, providers should refer to the Medi-Cal Rx Web Portal.