

# Policy Update of Remdesivir (Veklury) for the Outpatient Treatment of COVID-19 as a Pharmacy Benefit

#### March 1, 2023

Effective immediately, the Department of Health Care Services (DHCS) will no longer require a prior authorization (PA) for the reimbursement of Veklury as a pharmacy benefit.

Veklury is an antiviral drug that has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of SARS-CoV-2 viral testing. Veklury is for people who are hospitalized or not hospitalized with mild to moderate COVID-19 symptoms and are at high risk for progression to severe COVID-19, including hospitalization or death.

Initially, Veklury was FDA-approved for the treatment of hospitalized adults. On April 25, 2022, the FDA approved Veklury additionally for the treatment of pediatric patients.

Treatment duration for non-hospitalized patients is three days and is initiated as soon as possible after diagnosis of COVID-19, within seven days of symptom onset. See <u>FDA-Approved Drugs: Veklury</u> for a full list of drug specifications.

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

# **Important Billing Instructions**

- DHCS will reimburse Veklury for the treatment of COVID-19 when administered in accordance with FDA approval.
- A PA is no longer required. Code I restriction is required, attesting that the provider will meet the following requirements in accordance with FDA approval:
  - 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 (SNFs), home health care settings, and outpatient facilities such as infusion centers.
  - The treatment course is being initiated within seven 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 as clinically appropriate.
      - Monitor serum creatinine and creatinine clearance (CrCl).
      - Should not be administered if eGFR is less than 30 mL per minute.
    - Monitor for signs and symptoms of infusion reactions.
    - Hepatic function tests:
      - Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, and alkaline phosphatase.
      - Avoid use if  $ALT \ge 10$  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.

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- Veklury is restricted to a maximum of three days supply per dispensing for each diagnosis. Documentation is required justifying medical necessity for a longer treatment duration.
- All other policy details remain as previously implemented and published.

### Resources

- Veklury Package Insert
- Outpatient Product Information Guide.pdf (vekluryhcp.com)
- NIH COVID-19 Treatment Guidelines
- Veklury ordering and access information
  - 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 <u>C19Therapies@AmerisourceBergen.com</u> for more information.

For population of claim form fields other than those identified in this guidance, review the <u>Medi-Cal Rx Provider Manual</u>.

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

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

## **Contact Information**

You can call the Medi-Cal Rx Customer Service Center (CSC) at 1-800-977-2273, which is available 24 hours a day, 7 days a week, 365 days per year.

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For other questions, email Medi-Cal Rx Education & Outreach at MediCalRxEducationOutreach@magellanhealth.com.

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