| Reference number(s) |
| --- |
| 4330-A |

# Specialty Guideline Management
# Veklury

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Veklury | remdesivir |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (birth to less than 18 years of age weighing at least 1.5 kg) who are:

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

Note: the criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized patients receiving Veklury for the treatment of COVID-19 will be managed according to the member's inpatient benefit.

All other indications are considered experimental/investigational and not medically necessary.

| Reference number(s) |
| --- |
| 4330-A |

# Documentation

Submission of the following information is necessary to initiate the prior authorization review: medical records documenting positive COVID-19 infection, hepatic laboratory testing, and prothrombin time.

# Coverage Criteria

## Treatment of COVID-19 in Non-Hospitalized, High Risk Patients

Authorization of 30 days may be granted for the treatment of COVID-19 in non-hospitalized, high risk patients when all of the following criteria are met:

- Member has a confirmed active infection with COVID-19.
- Member weighs at least 1.5 kg.
- Member has at least one ongoing symptom consistent with COVID-19 within 7 days before treatment (e.g., fever, cough, fatigue, shortness of breath, sore throat, headache, myalgia/arthralgia).
- Member is non-hospitalized and is at high risk for progression to severe COVID-19 (e.g., chronic lung diseases, diabetes mellitus, obesity (BMI > 30), heart conditions), including hospitalization or death.
- Hepatic function and prothrombin time have been assessed prior to starting the requested medication and will be monitored while receiving therapy as clinically appropriate.
- Member will not receive a total duration of therapy greater than 3 days for an individual infection.
- The requested medication will not be administered in combination with chloroquine or hydroxychloroquine.
- The requested medication will be administered in a setting where severe hypersensitivity reactions, such as anaphylaxis, can be managed.

# References


1. Veklury [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2024.
2. Gottlieb RL, Vaca CE, Paredes R, et al. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. N Engl J Med. 2022;386(4):305-315.
3. NIH. The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/ Accessed: August 29, 2024.