

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Coronavirus Disease – Veklury Utilization Management Medical Policy

- Veklury® (remdesivir intravenous infusion – Gilead)

REVIEW DATE: 01/08/2025

OVERVIEW

Veklury, a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleotide analog RNA polymerase inhibitor, is indicated for the treatment of **coronavirus disease 2019 (COVID-19)** in patients from birth and weighing ≥ 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.¹

Dosing Information

The recommended dose of Veklury, for:¹

- Adults, or patients who are < 18 years of age and weigh ≥ 40 kg, is a single 200 mg loading dose given by intravenous (IV) infusion on Day 1, followed by 100 mg once daily, starting on Day 2.
- Patients at least 28 days old and weighing ≥ 3 kg and < 40 kg, is a single 5.0 mg/kg loading dose given by IV infusion on Day 1, followed by 2.5 mg/kg once daily, starting on Day 2.
- Patients at least 28 days old and weighing ≥ 1.5 kg and < 3 kg, is a single 2.5 mg/kg loading dose given by IV infusion on Day 1, followed by 1.25 mg/kg once daily, starting on Day 2.
- Patients < 28 days old and weighing ≥ 1.5 kg, is a single 2.5 mg/kg loading dose given by IV infusion on Day 1, followed by 1.25 mg/kg once daily, starting on Day 2.

Guidelines

The Infectious Disease Society of America (IDSA) has developed treatment guidelines for the management of COVID-19 and address the use of Veklury.² The IDSA guidelines recommend Veklury for hospitalized patients with COVID-19 who require supplemental oxygen. For patients receiving supplemental oxygen, Veklury is recommended for 5 days of treatment. The IDSA recommends against the initiation of Veklury in patients receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). In patients who require mechanical ventilation or ECMO after initiating Veklury, a full 10 day course of Veklury should be administered. The IDSA also recommends 3 days of Veklury for non-hospitalized patients with mild-to-moderate COVID-19 who are at high risk of progression.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Veklury. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. All reviews will be forwarded to the Medical Director for evaluation.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Veklury is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Coronavirus Disease 2019 (COVID-19), Treatment.** Approve for the duration noted if the patient meets ALL of the following (A, B, and C):
 - A) Patient weight is ≥ 1.5 kilograms; AND
 - B) Patient has tested positive for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); AND
 - C) Patient meets ONE of the following (i or ii):
 - i. Approve for 10 days if the patient is being treated in a hospital; OR
 - ii. Approve for 3 days if the patient meets BOTH of the following (a and b):
 - a) Patient is being treated in an outpatient setting; AND
 - b) Patient is at high risk of progression to severe COVID-19, according to the prescriber.

Dosing. Approve ONE of the following dosing regimens (A, B, C, or D):

- A) Adult, or patient who is < 18 years of age and weighs ≥ 40 kg and meets BOTH of the following (i and ii):
 - i. Loading dose: 200 mg intravenous dose given once on Day 1 of therapy; AND
 - ii. Maintenance dose: 100 mg intravenous dose given once daily beginning on Day 2; OR
- B) Patient is ≥ 28 days of age and weighs ≥ 3 kg and < 40 kg and meets BOTH of the following (i and ii):
 - i. Loading dose: 5 mg/kg intravenous dose given on Day 1 of therapy; AND
 - ii. Maintenance dose: 2.5 mg/kg intravenous dose given once daily beginning on Day 2; OR
- C) Patient is ≥ 28 days of age and weighs ≥ 1.5 kg and < 3 kg and meets BOTH of the following (i and ii):
 - i. Loading dose: 2.5 mg/kg intravenous dose given on Day 1 of therapy; AND
 - ii. Maintenance dose: 1.25 mg/kg intravenous dose given once daily beginning on Day 2; OR
- D) Patient is < 28 days of age and weighs ≥ 1.5 kg and meets BOTH of the following (i and ii):
 - i. Loading dose: 2.5 mg/kg intravenous dose given on Day 1 of therapy; AND
 - ii. Maintenance dose: 1.25 mg/kg intravenous dose given once daily beginning on Day 2.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Veklury is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Veklury intravenous infusion [prescribing information]. Foster City, CA: Gilead; December 2024.
2. Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Disease Society of America Guidelines on the treatment and management of patients with COVID-19. June 26, 2023. Available at: <https://www.idsociety.org/COVID19guidelines>. Accessed December 27, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023
Selected Revision	Coronavirus Disease 2019 (COVID-19), Treatment: The requirement that the patient is ≥ 3 kg was revised to ≥ 1.5 kg. Dosing regimen requirement that patient weighs ≥ 40 kg was revised to “Adult, or patient who is < 18 years of age and weighs ≥ 40 kg”; and removed criterion for hospitalized patients and outpatient treatment. Dosing regimen requirement that the patient weighs ≥ 3 kg and < 40 kg was revised to “Patient is ≥ 28 days of age and weighs ≥ 3 kg and < 40 kg”; and removed criterion for hospitalized patients and outpatient treatment. Added dosing regimen for patient ≥ 28 days of age and weighs ≥ 1.5 kg and < 3 kg. Added dosing regimen for patient < 28 days of age and weighs ≥ 1.5 kg.	03/13/2024
Annual Revision	No criteria changes.	01/08/2025