PRIOR AUTHORIZATION POLICY

POLICY: Coronavirus Disease – Veklury Prior Authorization Policy
- Veklury® (remdesivir intravenous infusion – Gilead)

REVIEW DATE: 12/13/2023, selected revision 03/13/2024

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 19 (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 of progression to severe COVID-19, including hospitalization or death.[1]

Guidelines

The Infectious Disease Society of America (IDSA) and the National Institutes of Health (NIH) have developed treatment guidelines for the management of COVID-19 and each address the use of Veklury.[2,3] Both the IDSA and NIH 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 and NIH recommend 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 and NIH also recommend 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 prescription benefit coverage of Veklury. 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 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.

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; August 2023.
2. COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. November 02, 2023. Available at: https://www.covid19treatmentguidelines.nih.gov/. Accessed on December 11, 2023.
3. 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 11, 2023.