VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Coronavirus Disease – Veklury Utilization Management Medical Policy
- Veklury® (remdesivir intravenous infusion – Gilead)

REVIEW DATE: 11/17/2021; selected revision 01/26/2022

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 ≥ 12 years of age and weighing ≥ 40 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]

Veklury was granted Emergency Use Authorization for the treatment of COVID-19 in patients ≥ 12 to < 18 years of age weighing ≥ 3.5 kg to < 40 kg, and in patients <12 years of age weighing ≥ 3.5 kg with positive results of direct SARS-CoV-2 testing 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.[4]

Dosing Information

The recommended dose of Veklury, for patients:

- Weighing ≥ 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.[1]
- Weighing ≥ 3.5 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.[4]

Veklury is given for a total of 5 days in patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO).[1,4] Therapy can be extended an additional 5 days in patients not demonstrating clinical improvement. Veklury is given for a total of 10 days in patients requiring mechanical ventilation or ECMO. In non-hospitalized patients, Veklury is given for a total of 3 days.

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 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 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 the following criteria (A, B, and C):
   - **A)** Patient weight is ≥ 3.5 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 or B):
   - **A)** Patient weighs ≥ 40 kg and meets all of the following (i, ii, and iii):
     - **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; AND
     - **iii.** Patient meets one of the following (a or b):
       - **a)** Hospitalized patient, treat for up to a total of 10 days; OR
       - **b)** Outpatient treatment, treat for a total of 3 days; OR
   - **B)** Patient weighs ≥ 3.5 kg and < 40 kg and meets all of the following (i, ii, and iii):
     - **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; AND
     - **iii.** Patient meets one of the following (a or b):
       - **a)** Hospitalized patient, treat for up to a total of 10 days; OR
       - **b)** Outpatient treatment, treat for a total of 3 days.

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; January 2022.
2. COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Available at: https://www.covid19treatmentguidelines.nih.gov/. Accessed on January 24, 2022.
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. January 18, 2022. Available at: https://www.idsociety.org/COVID19guidelines. Accessed January 24, 2022.
4. Fact sheet for healthcare providers Emergency Use Authorization (EUA) of Veklury (remdesivir) for the treatment of coronavirus disease 2019 (COVID-19) in pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg, with positive results of direct SARS-CoV-2 viral listing 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. U.S. Food and Drug Administration website. Available at: https://www.fda.gov/media/137566/download. Accessed on January 24, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/04/2020
Annual Revision	**Coronavirus Disease 2019 (COVID-19), Treatment:** Removed the qualifier "up to" from the loading and maintenance dose recommendations.	11/17/2021
Selected Revision	**Coronavirus Disease 2019 (COVID-19), Treatment:** Revised approval duration from 10 days to "Approve for the duration noted if the patient meets the following criteria." Removed requirement that the patient is ≥ 12 years of age. Added requirement that the patient's weight is ≥ 3.5 kg. Added "Approve for 10 days if the patient" is being treated in a hospital. Added additional option of approval that approves for 3 days if the patient is treated in an outpatient setting and the patient is at high risk of progression to severe COVID-19, according to the prescriber. Revised dosing regimen to require patient to weigh ≥ 40 kg and added treatment duration of up to a total of 10 days for hospitalized patients and a total of 3 days for outpatient treatment. Added additional treatment regimen for patients ≥ 3.5 kg and < 40 kg.	01/26/2022