Remdesivir (Veklury®) as an Outpatient Treatment of COVID-19 (Intravenous)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

Note: This policy addresses the use of Remdesivir (Veklury®) in the outpatient setting.

POLICY

- Remdesivir (Veklury®) for the treatment of high-risk, non-hospitalized patients with mild to moderate coronavirus disease 2019 (COVID-19) is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

CRITERIA FOR INITIAL APPROVAL

- For adults and pediatric members (birth to less than 18 years of age weighing at least 1.5 kg): **AND**
- Mild to moderate COVID-19 who are at high risk of progression* to severe disease; **AND**
- Positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) confirmed by molecular test (e.g., PCR, NAAT, etc.); **AND**
- The treatment course of remdesivir should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made and within 7 days of symptom onset: **AND**
- Hepatic function and PT have been taken prior to starting Remdesivir and will be monitored while receiving therapy as clinically appropriate.

** high risk of progression (e.g., obesity, diabetes mellitus, hypertension, immune compromise, chronic lung disease etc.) or age 60 years or older*

RENEWAL CRITERIA

Coverage cannot be renewed.

DOSAGE/ADMINISTRATION

*(Remdesivir may only be administered in a healthcare or hospital setting where severe hypersensitivity reactions, such as anaphylaxis, can be managed at a similar level of care as an inpatient setting **refer to prescribing information for dosing and administration)***

LENGTH OF AUTHORIZATION

Coverage will be provided for 3 infusions and may not be renewed.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-

label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

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ADDITIONAL INFORMATION

For additional information, also see:

FDA's approval of Veklury (remdesivir) for the treatment of COVID-19—The Science of Safety and Effectiveness https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#:~:text=hospitalization%20or%20death.-,For%20additional%20information%2C%20also%20see%3A%20FDA%E2%80%99s%20approval%20of%20Veklury%20(remdesivir)%20for%20the%20treatment%20of%20COVID%2D19%E2%80%94The%20Science%20of%20Safety%20and%20Effectiveness,-Federal%20Register%20notices

EUA –Archived Information https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#:~:text=Authorization%2D%2DArchived%20Information-,Emergency%20Use%20Authorization%2D%2DArchived%20Information,-Share

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2. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. *The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Non-hospitalized Patients With Mild to Moderate COVID-19;* Sections: Therapeutic Management of Nonhospitalized Adults with Covid 19, Therapeutic Management of Nonhospitalized Children with Covid 19 updated February 29, 2024 Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed April 8, 2024.
3. Gottlieb RL, Vaca CE, Paredes R, et al. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. N Engl J Med 2021: Available at: https://doi.org/10.1056/nejmoa2116846
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7. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medicalconditions.html. Healthcare providers should consider the benefit-risk for an individual patient.
8. U.S. Food and Drug Administrations (FDA). Press Announcements. https://www.fda.gov/news-events/press-announcements/fda-takes-actions-expand-use-treatment-outpatients-mild-moderate-covid-19. Retrieved January 25, 2022

9. U.S. Food and Drug Administrations (FDA) - EUA –Archived Information https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#:~:text=Authorization%2D%2DArchived%20Information-,Emergency%20Use%20Authorization%2D%2DArchived%20Information,-Share Retrieved January 25, 2022

EFFECTIVE DATE 8/30/2024

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