09-J3000-85

Original Effective Date: 01/15/21

Reviewed: 12/08/21

Revised: 06/15/22

Subject: Remdesivir (Veklury®)

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DESCRIPTION:

On October 22, 2020, the U.S. Food and Drug Administration (FDA) approved remdesivir (Veklury) for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. Remdesivir should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. Prior to approval, the FDA issued an Emergency Use Authorization (EUA) to permit the emergency use of remdesivir for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in adults and children hospitalized with severe disease. The EUA was reissued after remdesivir's FDA approval to allow for use to continue for suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized patients less than 12 years of age weighing at least 3.5 kg.

On April 25, 2022, the FDA expanded the approval of the remdesivir to include pediatric patients 28 days of age and older weighing at least 3 kilograms (about 7 pounds) with positive results of direct SARS-CoV-2 viral 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

As a result of the approval, the EUA covering the pediatric population was revoked.

POSITION STATEMENT:

Remdesivir (Veklury) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Indication for use is the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing
2. Member is hospitalized
3. Dose does not exceed 200 mg once on day 1 then 100 mg once daily for 9 days

Approval duration: 10 doses

Remdesivir **meets the definition of medical necessity** when used for the following designated Orphan Drug indication when the maximum FDA-approved dose is not exceeded:

1. Treatment of Ebola

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

Dosage

- Recommended dosage in adults and pediatric patients 12 years of age and older and weighing at least 40 kg: a single loading dose of 200 mg on Day 1 followed by once-daily maintenance doses of 100 mg from Day 2 infused over 30 to 120 minutes.
- For patients not requiring invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days.
- For patients requiring invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.
- Administer via intravenous (IV) infusion over 30 to 120 minutes.

Dose Adjustments

- Renal impairment: Use is not recommended in patients with eGFR less than 30 mL/min.

Drug Availability

- For injection: 100 mg of remdesivir as a lyophilized powder, in a single-dose vial.
- Injection: 100 mg/20 mL (5 mg/mL) remdesivir, in a single-dose vial.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Contraindicated in patients with a history of clinically significant hypersensitivity reactions to remdesivir or any components of the product.

Precautions/Warnings

- Hypersensitivity
- Increased risk of transaminase elevations
- Risk of reduced antiviral activity when coadministration of remdesivir and chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on cell culture data demonstrating an antagonistic effect of chloroquine on the intracellular metabolic activation and antiviral activity

BILLING/CODING INFORMATION:

HCPCS Coding

J0248	Injection, remdesivir, 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

U07.1	COVID-19

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: BCBSF has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

1. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2021 [cited 11/11/21]. Available from: http://www.clinicalpharmacology.com/.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine; 2000 Feb 29 - [cited 1111/21]. Available from: http://clinicaltrials.gov/.
3. Gilead Sciences. Veklury (remdesivir) injection. 2021. [cited 11/11/21]. In: DailyMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c0978fa8-53ff-4ca2-82a7-567fd3e958ca&audience=consumer
4. U.S. Food and Drug Administration, Center for Drug Evaluation and Research [cited 5/11/20]. Remdesivir EUA Letter. Available from: https://www.fda.gov/media/137564/download
5. U.S. Food and Drug Administration, Center for Drug Evaluation and Research [cited 5/11/20]. Fact Sheet for Health Care Providers. Emergency Use Authorization (EUA) of Remdesivir (GS-5734). Available from: https://www.fda.gov/media/137566/download

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 12/08/21.

GUIDELINE UPDATE INFORMATION:

01/15/21	New Medical Coverage Guideline.
01/15/22	Review and revision; updated references.
02/15/22	Updated coding.
06/15/22	Updated description.