Veklury (remdesivir)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Veklury (remdesivir) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Treatment of adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with coronavirus disease 2019 (COVID-19) requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review: medical records documenting positive COVID-19 infection, estimated glomerular filtration rate (eGFR), hepatic laboratory testing, and prothrombin time.

Criteria for Initial Approval
Treatment of COVID-19
Authorization of 30 days may be granted for treatment of COVID-19 when all of the following criteria are met:
   A. Member has a confirmed active infection with COVID-19
   B. Member is 12 years of age or older and weighs at least 40 kg
   C. Member has eGFR ≥ 30 mL/min
D. Member is sufficiently ill to require hospitalization
E. Renal function, hepatic function, and prothrombin time have been taken prior to starting Veklury and will be monitored while receiving therapy as clinically appropriate
F. Member will receive a loading dose of 200mg on Day 1 followed by maintenance dose of 100mg per day starting Day 2
G. Member will not receive a total duration of therapy of greater than 10 days for an individual infection
H. Veklury will not be administered in combination with chloroquine or hydroxychloroquine
I. Veklury will be administered in a hospital or healthcare setting capable of providing acute care comparable to inpatient hospital care

Veklury (remdesivir) may not be granted when the above criteria are not met and for all other indications.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

CLINICAL RATIONALE

Veklury (remdesivir), an inhibitor of the SARS-CoV-2 RNA-dependent RNA polymerase, was approved by the United States Food and Drug Administration (FDA) on October 22, 2020 for the treatment of COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) requiring hospitalization. Under its approval, Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. An Emergency Use Authorization (EUA) was initially given to remdesivir on May 1, 2020. While not FDA-approved, the EUA for Veklury continues to authorize the emergency use for treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. Clinical trials assessing the safety and efficacy of Veklury in this pediatric patient population are ongoing.

The recommended dose of Veklury is a single loading dose of 200 mg on day 1 via intravenous (IV) infusion followed by once-daily maintenance doses of 100 mg from day 2 via IV infusion. The recommended treatment duration for patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO) 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. The recommended total treatment duration for patients requiring invasive mechanical ventilation and/or ECMO is 10 days.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.
- J3490 – Unclassified drugs (when specified as [Veklury] remdesivir)
- XW043E5 – Introduction of Remdesivir Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 5

REFERENCES