Policy Number	**RX501.130**
Policy Effective Date	**11/01/2025**

Remdesivir

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Related Policies (if applicable)
None

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Ohio, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated, and coverage is not required for non-formulary drugs.

Coverage

Remdesivir (Veklury®) **may be considered medically necessary** for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (birth to less than 18 years of age weighing at least 1.5 kg):

- Who are hospitalized; or
- Who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

Remdesivir (Veklury®) **is experimental, investigational and/or unproven** for all other non-Food and Drug Administration (FDA) indications.

Policy Guidelines

Per the U.S. Food and Drug Administration label, remdesivir (Veklury®) may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system as necessary.

Description

Remdesivir is an antiviral medication first developed to treat Ebola. It later showed promise fighting severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome (MERS), illnesses caused by coronaviruses, in animal studies. Once severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) invades a human cell, it replicates with the help of a viral enzyme called RdRp (RNA-dependent RNA-polymerase). Remdesivir is designed to slow or stop the virus from creating copies of itself by blocking this particular enzyme. (2)

Regulatory Status

Remdesivir (Veklury®) received Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) on May 1, 2020, for the treatment of hospitalized patients with severe 2019 coronavirus disease (COVID-19). On Oct. 22, 2020, the FDA approved Veklury® (remdesivir) for adults and pediatric patients (12 years and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Under the approval, Veklury® should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. In January 2022, Veklury was approved by the FDA for the treatment of non-hospitalized patients at high risk for COVID-19 disease progression. (3)

In April 2022, the FDA approved a revision of the indications for Veklury for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) 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. The FDA label now states Veklury may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. (3)

On July 14, 2023, the FDA approved an expanded indication for the use of Veklury to include patients with severe renal impairment, including those on dialysis. With this approval, Veklury is now the first and only approved antiviral COVID-19 treatment that can be used across all stages of renal disease. On August 24, 2023, the FDA then expanded the use of Veklury to include people with mild, moderate, and severe hepatic impairment with no dose adjustments in treatment of COVID-19. This approval further supports the safety profile of Veklury as the first and only approved antiviral COVID-19 treatment that can be used across all stages of liver disease. (3)

In February 2024, the FDA approved a label expansion for the use of Veklury in pediatric patients from birth to less than 18 years of age and weighing at least 1.5 kg. (1)

Rationale

This medical policy is based on the Food and Drug Administered labeled indications for Veklury® (remdesivir).

Veklury (1)
The efficacy and safety of Veklury were evaluated in the trials summarized in Table 1.

Table 1. Trials Conducted with Veklury in Subjects with COVID-19

Trial	Population	Trial Arms (N)	Timepoint
NIAID ACTT-1[a] (NCT04280705)	Hospitalized with mild/moderate and severe COVID-19	Veklury 10 Days (532) Placebo (516)	29 Days after Randomization
GS-US-540-5773[b] (NCT04292899)	Hospitalized with severe COVID-19	Veklury 5 Days (200) Veklury 10 Days (197)	Day 14
GS-US-540-5774[b] (NCT04292730)	Hospitalized with moderate COVID-19	Veklury 5 Days (191) Veklury 10 Days (193) Standard of care (200)	Day 11
GS-US-540-9012[a] (NCT04501952)	Non-hospitalized with mild-to-moderate COVID-19 and at high	Veklury 3 Days (279) Placebo (283)	Day 28

	risk for progression to severe disease		
GS-US-540-5823 (Cohorts 1-8)[c] (NCT04431453)	Hospitalized pediatric subjects from birth to <18 years of age and weighing at least 1.5 kg with COVID-19	Veklury up to 10 Days (58)	Day 10

COVID-19: coronavirus disease 2019; kg: kilogram.
[a] Randomized, double-blind, placebo-controlled trial.
[b] Randomized, open-label trial.
[c] Open-label trial, descriptive outcome analyses.

National Institute of Allergy and Infectious Diseases (NIAID) Adaptive Covid-19 Treatment Trial (ACTT-1) Study in Hospitalized Subjects with Mild/Moderate and Severe COVID-19

A randomized, double-blind, placebo-controlled clinical trial (ACTT-1, NCT04280705) of hospitalized adult subjects with confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and mild, moderate, or severe COVID-19 compared treatment with Veklury for 10 days (n=541) with placebo (n=521). Mild/moderate disease was defined as pulse oximetry (SpO_2) >94% and respiratory rate <24 breaths/minute without supplemental oxygen; severe disease was defined as an SpO_2 ≤94% on room air, a respiratory rate ≥24 breaths/minute, an oxygen requirement, or a requirement for mechanical ventilation. Subjects had to have at least one of the following to be enrolled in the trial: radiographic infiltrates by imaging, SpO_2 ≤94% on room air, a requirement for supplemental oxygen, or a requirement for mechanical ventilation. Subjects treated with Veklury received 200 mg on Day 1 and 100 mg once daily on subsequent days, for 10 days of treatment via intravenous infusion. Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to the completion of 10 days of treatment.

At baseline, mean age was 59 years (with 36% of subjects aged 65 or older); 64% of subjects were male, 53% were White, 21% were Black, and 13% were Asian; 24% were Hispanic or Latino; 105 subjects had mild/moderate disease (10% in both treatment groups); 957 subjects had severe disease (90% in both treatment groups). Subjects in this trial were unvaccinated. A total of 285 subjects (27%) (n=131 received Veklury) were on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). The most common comorbidities were hypertension (51%), obesity (45%), and type 2 diabetes mellitus (31%); the distribution of comorbidities was similar between the two treatment groups.

The primary clinical endpoint was time to recovery within 29 days after randomization. Recovery was defined as discharged from the hospital without limitations on activities, discharged from the hospital with limitations on activities and/or requiring home oxygen, or hospitalized but not requiring supplemental oxygen and no longer requiring ongoing medical care. The median time to recovery was 10 days in the Veklury group compared to 15 days in the placebo group (recovery rate ratio 1.29 [95% confidence interval [CI], 1.12 to 1.49], p<0.001). Among subjects with mild/moderate disease at enrollment (n=105), the median time to

recovery was 5 days in both the Veklury and placebo groups (recovery rate ratio 1.22 [95% CI, 0.82 to 1.81]). Among subjects with severe disease at enrollment (n=957), the median time to recovery was 11 days in the Veklury group compared to 18 days in the placebo group (recovery rate ratio 1.31 [95% CI, 1.12 to 1.52]).

A key secondary endpoint was clinical status on Day 15 assessed on an 8-point ordinal scale consisting of the following categories:

1. Not hospitalized, no limitations on activities;
2. Not hospitalized, limitation on activities and/or requiring home oxygen;
3. Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care;
4. Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise);
5. Hospitalized, requiring supplemental oxygen;
6. Hospitalized, on noninvasive ventilation or high-flow oxygen devices;
7. Hospitalized, on invasive mechanical ventilation or ECMO; and
8. Death.

Overall, the odds of improvement in the ordinal scale were higher in the Veklury group at Day 15 when compared to the placebo group (odds ratio 1.54 [95% CI, 1.25 to 1.91]).

Overall, 29-day mortality was 11% for the Veklury group versus (vs) 15% for the placebo group (hazard ratio 0.73 [95% CI, 0.52 to 1.03]).

Study GS-US-540-5773 in Hospitalized Subjects with Severe COVID-19

A randomized, open-label multi-center clinical trial (Study 5773, NCT04292899) in adult subjects with confirmed SARS-CoV-2 infection, an SpO_2 of ≤94% on room air, and radiological evidence of pneumonia compared 200 subjects who received Veklury for 5 days with 197 subjects who received Veklury for 10 days. Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to completion of their protocol-defined duration of treatment. Subjects on mechanical ventilation at screening were excluded. All subjects received 200 mg of Veklury on Day 1 and 100 mg once daily on subsequent days via intravenous infusion, plus standard of care.

At baseline, the median age of subjects was 61 years (range, 20 to 98 years); 64% were male, 75% were White, 12% were Black, and 12% were Asian; 22% were Hispanic or Latino. More subjects in the 10-day group than the 5-day group required invasive mechanical ventilation or ECMO (5% vs 2%), or high-flow oxygen support (30% vs 25%), at baseline. Median duration of symptoms and hospitalization prior to first dose of Veklury were similar across treatment groups.

The primary endpoint was clinical status on Day 14 assessed on a 7-point ordinal scale consisting of the following categories:

1. Death;
2. Hospitalized, receiving invasive mechanical ventilation or ECMO;

3. Hospitalized, receiving noninvasive ventilation or high-flow oxygen devices;
4. Hospitalized, requiring low-flow supplemental oxygen;
5. Hospitalized, not requiring supplemental oxygen but receiving ongoing medical care (related or not related to COVID-19);
6. Hospitalized, requiring neither supplemental oxygen nor ongoing medical care (other than that specified in the protocol for remdesivir administration); and
7. Not hospitalized.

Overall, after adjusting for between-group differences at baseline, subjects receiving a 5-day course of Veklury had similar clinical status at Day 14 as those receiving a 10-day course (odds ratio for improvement 0.75 [95% CI 0.51 to 1.12]). There were no statistically significant differences in recovery rates or mortality rates in the 5-day and 10-day groups once adjusted for between-group differences at baseline. All-cause mortality at Day 28 was 12% vs 14% in the 5- and 10-day treatment groups, respectively.

Study GS-US-540-5774 in Hospitalized Subjects with Moderate COVID-19

A randomized, open-label multi-center clinical trial (Study 5774, NCT04292730) of hospitalized adult subjects with confirmed SARS-CoV-2 infection, SpO_2 >94% and radiological evidence of pneumonia compared treatment with Veklury for 5 days (n=191) and treatment with Veklury for 10 days (n=193) with standard of care (n=200). Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to completion of their protocol-defined duration of treatment. Subjects treated with Veklury received 200 mg on Day 1 and 100 mg once daily on subsequent days via intravenous infusion.

At baseline, the median age of subjects was 57 years (range, 12 to 95 years); 61% were male, 61% were White, 19% were Black, and 19% were Asian; 18% were Hispanic or Latino. Subjects in this trial were unvaccinated. Baseline clinical status, oxygen support status, and median duration of symptoms and hospitalization prior to first dose of Veklury were similar across treatment groups.

The primary endpoint was clinical status on Day 11 assessed on a 7-point ordinal scale consisting of the following categories:

1. Death;
2. Hospitalized, receiving invasive mechanical ventilation or ECMO;
3. Hospitalized, receiving noninvasive ventilation or high-flow oxygen devices;
4. Hospitalized, requiring low-flow supplemental oxygen;
5. Hospitalized, not requiring supplemental oxygen but receiving ongoing medical care (related or not related to COVID-19);
6. Hospitalized, requiring neither supplemental oxygen nor ongoing medical care (other than that specified in the protocol for remdesivir administration); and
7. Not hospitalized.

Overall, the odds of improvement in the ordinal scale were higher in the 5-day Veklury group at Day 11 when compared to those receiving only standard of care (odds ratio 1.65 [95% CI 1.09 to

2.48], p=0.017). The odds of improvement in clinical status with the 10-day treatment group when compared to those receiving only standard of care were not statistically significant (odds ratio 1.31 [95% CI 0.88 to 1.95]). All-cause mortality at Day 28 was ≤2% in all treatment groups.

Study GS-US-540-9012 In Non-Hospitalized Subjects with Mild-to-Moderate COVID-19 and at High Risk for Progression to Severe Disease

A randomized, double-blind, placebo-controlled, clinical trial (Study 9012) evaluated Veklury 200 mg once daily for 1 day followed by Veklury 100 mg once daily for 2 days (for a total of 3 days of intravenously administered therapy) in 554 adult and 8 pediatric subjects (12 years of age and older and weighing at least 40 kg) who were non-hospitalized, had mild-to moderate COVID-19, were symptomatic for COVID-19 for ≤7 days, had confirmed SARS-CoV-2 infection, and had at least one risk factor for progression to hospitalization. Risk factors for progression to hospitalization included age ≥60 years, obesity (BMI ≥30), chronic lung disease, hypertension, cardiovascular or cerebrovascular disease, diabetes mellitus, immunocompromised state, chronic mild or moderate kidney disease, chronic liver disease, current cancer, and sickle cell disease. Subjects who received, required, or were expected to require supplemental oxygen were excluded from the trial. Subjects were randomized in a 1:1 manner, stratified by residence in a skilled nursing facility (yes/no), age (<60 vs ≥60 years), and region (U.S. vs ex-U.S.) to receive Veklury (n=279) or placebo (n=283), plus standard of care.

At baseline, mean age was 50 years (with 30% of subjects aged 60 or older); 52% were male, 80% were White, 8% were Black, and 2% were Asian; 44% were Hispanic or Latino; median body mass index was 30.7 kg/m^2. Subjects in this trial were unvaccinated. Veklury or placebo was first administered to subjects in outpatient facilities (84%), home healthcare settings (13%), or skilled nursing facilities (3%). The most common comorbidities were diabetes mellitus (62%), obesity (56%), and hypertension (48%). Median (Q1, Q3) duration of symptoms prior to treatment was 5 (3, 6) days; median viral load was 6.3 $\log_{10}$ copies/mL at baseline. The baseline demographics and disease characteristics were well balanced across the Veklury and placebo treatment groups.

The primary endpoint was the proportion of subjects with COVID-19 related hospitalization (defined as at least 24 hours of acute care) or all-cause mortality through Day 28. Events occurred in 2 (0.7%) subjects treated with Veklury compared to 15 (5.3%) subjects concurrently randomized to placebo (hazard ratio 0.134 [95% CI 0.031 to 0.586]; p=0.0076). No deaths were observed through Day 28.

Study GS-US-540-5823 in Hospitalized Pediatric Subjects with COVID-19

The primary objectives of this Phase 2/3 single-arm, open-label clinical study (Study GS-US-540-5823) were to evaluate pharmacokinetics and safety of up to 10 days of treatment with Veklury in pediatric subjects. A total of 58 pediatric subjects from birth (including preterm to term infants) to <18 years of age and weighing at least 1.5 kg with confirmed SARS-CoV-2 infection and mild, moderate, or severe COVID-19 was evaluated in eight cohorts:

- *Cohorts 1-4, 8; infants, children, and adolescents:* Subjects ≥12 years and weighing ≥40 kg (n=12); subjects <12 years and weighing ≥40 kg (n=5); subjects ≥28 days and weighing ≥20

to <40 kg (n=12); subjects ≥28 days and weighing ≥12 to <20 kg (n=12); and subjects ≥28 days and weighing ≥3 to <12 kg (n=12). Subjects weighing ≥40 kg received 200 mg of Veklury on Day 1 followed by Veklury 100 mg once daily on subsequent days; subjects weighing ≥3 kg to <40 kg received Veklury 5 mg/kg on Day 1 followed by Veklury 2.5 mg/kg once daily on subsequent days.

- *Cohorts 5-7; neonates and infants:* Subjects 14 to <28 days old, Gestational age (GA) >37 weeks, and weighing ≥2.5 kg (n=3); subjects <14 days old, GA >37 weeks, and weighing ≥2.5 kg at birth (n=1); and subjects <56 days old, GA ≤37 weeks, and weighing ≥1.5 kg at birth (n=1). Subjects 14 to <28 days old, GA >37 weeks, and weighing ≥2.5 kg received Veklury 5 mg/kg on Day 1 followed by Veklury 2.5 mg/kg once daily on subsequent days. Subjects <14 days old, GA >37 weeks, and weighing at least 2.5 kg at birth, and subjects <56 days old, GA ≤37 weeks, and weighing ≥1.5 kg at birth, received Veklury 2.5 mg/kg on Day 1 followed by Veklury 1.25 mg/kg once daily on subsequent days.

Assessments occurred at the following intervals: Screening; Day 1 (Baseline); Days 2-10, or until discharge, whichever came earlier; Follow-Up on Day 30 (±5). Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to the completion of 10 days of treatment.

Infants, children, and adolescents: At baseline, median age was 7 years (Q1, Q3: 2 years, 12 years); 57% were female, 70% were White, 30% were Black, and 44% were Hispanic or Latino; median weight was 25 kg (range: 4 to 192 kg). Subjects in this trial were unvaccinated. A total of 12 subjects (23%) were on invasive mechanical ventilation, 18 (34%) were on non-invasive ventilation or high-flow oxygen; 10 (19%) were on low-flow oxygen; and 13 (25%) were on room air, at baseline. The overall median (Q1, Q3) duration of symptoms and hospitalization prior to first dose of Veklury was 5 (3, 7) days and 1 (1, 3) day, respectively.

The descriptive outcome analyses showed treatment with Veklury for up to 10 days resulted in an overall median (Q1, Q3) change from baseline in clinical status (assessed on a 7-point ordinal scale ranging from death [score of 1] to ventilatory support and decreasing levels of oxygen to hospital discharge [score of 7]) of +2.0 (1.0, 4.0) points on Day 10.

Recovery (defined as an improvement from a baseline clinical status score of 2 through 5 to a score of 6 or 7, or an improvement from a baseline score of 6 to a score of 7) was reported for 62% of subjects on Day 10; median (Q1, Q3) time to recovery was 7 (5, 16) days.

Overall, 60% of subjects were discharged by Day 10, and 83% of subjects were discharged by Day 30. Three subjects (6%) from Cohorts 1-4 and Cohort 8 died during the study.

Neonates and infants: At baseline, subjects ranged in age from 12 to 30 days; 3/5 were female, 4/5 were White, 1/5 was Black; weight ranged from 2.2 to 3.5 kg. Three subjects were on invasive mechanical ventilation and 2 were on high-flow oxygen. The duration of symptoms and hospitalization prior to first dose of Veklury ranged from 2 to 9 days and 1 to 9 days, respectively.

The descriptive outcome analyses showed treatment with Veklury for up to 10 days resulted in recovery (defined as an improvement from a baseline clinical status score of 2 through 5 to a score of 6 or 7, or an improvement from a baseline score of 6 to a score of 7) for 3 subjects, including for one subject by Day 10. Time to recovery ranged from 9 to 19 days.

Overall, a total of 3 subjects were discharged by Day 30, of which one subject was discharged by Day 10. No subjects from Cohorts 5-7 died during the study.

Summary of Evidence

Based on the clinical studies provided to the U.S. Food and Drug Administration, Veklury® (remdesivir) may be considered medically necessary for adults and pediatric individuals (birth to less than 18 years of age weighing at least 1.5 kg) for the treatment of coronavirus disease 2019 (COVID-19) who are hospitalized or are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19 including hospitalization and death. It is considered experimental, investigational and/or unproven for all other non-FDA approved indications. The FDA label specifically states Veklury (remdesivir) may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system as necessary.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	J0248

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

U.S. Food and Drug Administration Label:

1. U.S. Food and Drug Administration. Drugs@FDA. Highlights of Prescribing Information Veklury® (8/2025). Available at <https://www.accessdata.fda.gov> (accessed August 29, 2025).

Other:

2. Eastman R, Roth J, Brimacombe K, et al. Remdesivir: A Review of Its Discovery and Development Leading to Emergency Use Authorization for Treatment of COVID-19. ACS Cent Sci. 2020 May 27; 6(5):672-683. PMID 32483554
3. Veklury FDA Approval History. Available at <https://www.drugs.com> (assessed January 21, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/01/2025	Document updated with literature review. The following changes were made to Coverage: 1) Removed “with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing” from coverage criteria statement; 2) Revised the experimental, investigational and/or unproven statement. No new references added; others updated.
03/01/2025	Document updated with literature review. The following change was made to Coverage: Expanded the medically necessary statement for Remdesivir (Veklury®) in pediatric patients to include "Birth to less than 18 years of age weighing at least 1.5 kg". Added reference 3; others updated.
03/15/2024	Document updated with literature review. Coverage unchanged. Reference 5 added. Title changed from: Veklury®.
07/01/2023	Reviewed. No changes.
12/15/2022	Document updated with literature review. Coverage revised: Veklury® (Remdesivir) may be considered medically necessary for adults and pediatric patients (28 days of age and older and weighing at least 3 kg) for the treatment of coronavirus disease 2019 (COVID-19) 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 and death. It is considered experimental, investigational and/or unproven for all other indications. The FDA label specifically states Veklury (Remdesivir) may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as

	anaphylaxis, and the ability to activate the emergency medical system (EMS) as necessary. References revised; none added.
01/01/2022	Reviewed. No changes.
04/01/2021	New medical document. Veklury® (Remdesivir) may be considered medically necessary 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. It is considered experimental, investigational and/or unproven for all other indications and in other healthcare settings unable to provide acute care comparable to inpatient hospital care. The FDA label specifically states Veklury (Remdesivir) should only be administered in a hospital or healthcare setting capable of providing acute care comparable to inpatient hospital care.