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 Last P&T Approval/Version: 01/29/2025
 Next Review Due By: 01/2026
 Policy Number: C20763-A

Veklury (remdesivir)

PRODUCTS AFFECTED

Veklury (remdesivir), remdesivir

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Coronavirus disease 2019 (COVID-19)

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. INPATIENT HOSPITAL CORONAVIRUS DISEASE (COVID-19) TREATMENT:

1. Prescriber is requesting drug for treatment of suspected or laboratory-confirmed coronavirus disease 2019 (COVID-19) infection
 AND

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2. Documentation that the severity of infection requires hospitalization or a healthcare setting capable of providing acute care comparable to inpatient hospital care
AND
3. Documentation member weighs at least 1.5 kg

B. OUTPATIENT CORONAVIRUS DISEASE (COVID-19) TREATMENT ^(2,3):

1. Documentation of SARS-CoV-2 infection confirmed by a molecular diagnostic assay
AND
2. Prescriber attestation member has not had a previous hospitalization for COVID-19 treatment, member has not previously received treatment for COVID-19 (monoclonal antibodies or antiviral therapy), AND member has not received a SARS CoV-2 vaccine.
AND
3. Documentation member has at least ONE preexisting risk factor for progression to severe COVID-19: age greater than or equal to 60 years, hypertension, cardiovascular or cerebrovascular disease, diabetes mellitus, obesity (BMI \geq 30), immune compromise, chronic mild or moderate kidney disease, chronic liver disease, chronic lung disease, current cancer or sickle cell disease.
AND
4. Documentation member has at least one symptom consistent with COVID-19
AND
5. Documentation first infusion will be within 7 days of symptom onset
AND
6. Prescriber attestation member has been counseled and has agreed to be compliant with the full course of 3 days of infusions
AND
7. Prescriber attestation that NIH COVID-19 treatment guideline recommended first line oral antiviral therapies are not available or member has a documented medical contraindication to first line oral antiviral therapies
AND
8. Prescriber attestation that the Omicron variant of SARS-Cov-2 is the prominent variant in the members region
AND
9. Documentation member weighs at least 1.5 kg

CONTINUATION OF THERAPY:

N/A: Each new infection treatment should be a new review

DURATION OF APPROVAL:

Initial authorization: INPATIENT 10 days, OUTPATIENT 3 days, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

No restriction

QUANTITY:

INPATIENT TREATMENT:

The recommended dosage for adults and pediatric patients weighing at least 40 kg is a single loading dose of Veklury 200 mg on Day 1 via intravenous infusion followed by once-daily maintenance doses of Veklury 100mg from Day 2 via intravenous infusion

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Pediatric patients birth to less than 18 years of age weighing 1.5 kg to less than 40 kg: a single loading dose of Veklury 2.5 mg/kg or 5 mg/kg on Day 1 followed by once-daily maintenance doses of Veklury 1.25 mg/kg or 2.5 mg/kg from Day 2 via intravenous infusion

*** When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy. 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.

OUTPATIENT TREATMENT:

Adults and pediatric patients weighing at least 40kg: 200 mg on day 1 followed by 100 mg on days 2 and 3
Pediatric patients birth to less than 18 years of age weighing 1.5 kg to less than 40 kg: 2.5 mg/kg or 5 mg/kg on day 1, followed by 1.25 mg/kg or 2.5 mg/kg on days 2 and 3

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is either inpatient or a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous Infusion

DRUG CLASS:

Misc. Antivirals

FDA-APPROVED USES:

Indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (birth to less than 18 years of age weighing at least 1.5 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.

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

January 2022 update:

The PINETREE trial studied remdesivir in nonhospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease. In this trial patients were given remdesivir 200mg IV on

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day 1, 100mg on days 2 and 3. The study was done from September 18, 2020, through April 8, 2021.

Eligible patients were 12 years of age or older and had at least one preexisting risk factor for progression to severe Covid-19 or were 60 years of age or older, regardless of whether they had other risk factors. Risk factors included hypertension, cardiovascular or cerebrovascular disease, diabetes mellitus, obesity (a body-mass index of ≥ 30), immune compromise, chronic mild or moderate kidney disease, chronic liver disease, chronic lung disease, current cancer, or sickle cell disease. Eligible patients had at least one ongoing symptom consistent with Covid-19, with onset of the first symptom within 7 days before randomization. Eligible patients had SARS-CoV-2 infection confirmed by a molecular diagnostic assay within 4 days before screening. Patients were ineligible if they were receiving or were expected to receive supplemental oxygen or hospital care at the time of screening. Patients were also ineligible if they had had a previous hospitalization for Covid-19, had previously received treatment for Covid-19 (including investigational agents), or had received a SARSCoV-2 vaccine.

A total of 562 patients who underwent randomization and received at least one dose of remdesivir or placebo were included in the analyses: 279 patients in the remdesivir group and 283 in the placebo group. The most common coexisting conditions were diabetes mellitus (61.6%), obesity (55.2%), and hypertension (47.7%).

Covid-19–related hospitalization or death from any cause occurred in 2 patients (0.7%) in the remdesivir group and in 15 (5.3%) in the placebo group (hazard ratio, 0.13; 95% confidence interval [CI], 0.03 to 0.59; $P=0.008$). A total of 4 of 246 patients (1.6%) in the remdesivir group and 21 of 252 (8.3%) in the placebo group had a Covid-19–related medically attended visit by day 28 (hazard ratio, 0.19; 95% CI, 0.07 to 0.56). No patients had died by day 28.

Adverse events occurred in 42.3% of the patients in the remdesivir group and in 46.3% of those in the placebo group.

Gilead Statement on Veklury® (Remdesivir) and the SARS-CoV-2 Omicron Variant

Foster City, Calif., December 1, 2021 –

Gilead has conducted an analysis of genetic information currently available for the Omicron variant and found no additional prevalent mutations in the viral RNA polymerase compared to previous SARS-CoV-2 variants. This suggests that Veklury® (remdesivir) will continue to be active against the Omicron variant and Gilead will conduct laboratory testing to confirm this analysis.

Veklury directly inhibits the SARS-CoV-2 replication inside infected cells by targeting the viral RNA polymerase. Initial genetic analysis of more than 200 available sequences of the Omicron variant isolates, including those from South Africa, Asia and Europe, has shown that no new mutations are present in the Omicron variant that are expected to alter the SARS-CoV-2 viral RNA polymerase compared to previous variants. This suggests that Veklury will continue to be active against the Omicron variant and Gilead will continue to analyze additional genetic sequences of the Omicron variant as they become available. Gilead conducts these analyses to ensure rapid and transparent updates on the potential effectiveness of Veklury.

In addition to genetic analyses, Gilead continues to experimentally evaluate the activity of Veklury against identified SARS-CoV-2 variants through in vitro antiviral testing. Veklury's antiviral activity has been confirmed in vitro against all major previously identified variants of SARS-CoV-2 including Alpha, Beta, Gamma, Delta, and Epsilon. Due to the similarities in the viral RNA polymerase, these laboratory findings suggest that Veklury will also continue to be active against the Omicron variant and Gilead will conduct laboratory testing to confirm this analysis.

Gilead is working with experts in governments and academia to obtain viral isolates and conduct in vitro laboratory testing of Veklury's antiviral activity against the Omicron variant, which requires additional time.

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As soon as the testing is complete, Gilead will share the data with regulatory agencies, treating physicians and public health authorities.

To date, no major genetic changes have been identified in any of the known SARS-CoV-2 variants of concern and variants of interest that would significantly alter the viral RNA polymerase targeted by Veklury. In contrast, all identified variants show mutations at different locations in the SARS-CoV-2 spike protein, which is on the outer surface of the virus and serves as a target for all neutralizing anti-SARS-CoV-2 antibodies.

NIH- The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19

Previous Update: December 30, 2021

Remdesivir is expected to be active against the Omicron VOC, although in vitro and in vivo data are currently limited. Because remdesivir requires IV infusion for 3 consecutive days, there may be logistical constraints to administering remdesivir in many settings, but it is an option if ritonavir-boosted nirmatrelvir (Paxlovid) and sotrovimab are not available.

Remdesivir is currently approved by the FDA for use in hospitalized individuals, and outpatient treatment would be an off-label indication.

Last Updated: December 28, 2022

Patient Disposition	Panel's Recommendation
Patients who are at high risk of progressing to severe COVID-19	Preferred therapies. Listed in order of preference: <ul style="list-style-type: none">• Ritonavir-boosted nirmatrelvir (Paxlovid) (AIIa)• Remdesivir (BIIa) Alternative therapy. For use when the preferred therapies are not available, feasible to use, or clinically appropriate: <ul style="list-style-type: none">• Molnupiravir (CIIa)

The Panel favors the use of ritonavir-boosted nirmatrelvir in most high-risk, nonhospitalized patients with mild to moderate COVID-19. When ritonavir-boosted nirmatrelvir is not clinically appropriate (e.g., because of significant drug-drug interactions), the Panel recommends using remdesivir. Ritonavir-boosted nirmatrelvir has high efficacy; has been shown to reduce hospitalization and death when administered to high-risk, unvaccinated, nonhospitalized patients within 5 days of symptom onset;¹¹ and is an oral medication, whereas remdesivir requires intravenous (IV) administration.

The Panel's recommendation for remdesivir is based on a Phase 3, randomized, placebo-controlled trial that reported high clinical efficacy in high-risk patients with COVID-19 who were unvaccinated.^{11,12} However, in some settings, daily IV administration of remdesivir for 3 days may be a logistical challenge. The Panel recommends **molnupiravir** as a therapeutic option when the other recommended antiviral treatment options are not available, feasible to use, or clinically appropriate (**CIIa**). Molnupiravir appears to have lower clinical efficacy than the other treatment options, although no randomized studies directly compare these therapies.

This recommendation is affirmed in the November 2, 2023 update.

The NIH archived the guidelines on August 16, 2024.

NIAID ACTT-1 Study in 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 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 SpO₂ >94% and respiratory rate <24 breaths/minute without

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supplemental oxygen; severe disease was defined as an SpO₂ ≤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, SpO₂ ≤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). A total of 285 subjects (27%) (n=131 received VEKLURY) were on invasive mechanical ventilation or 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. 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).

A total of 285 subjects (27%) (n=131 received VEKLURY) were on invasive mechanical ventilation or 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% 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 vs 15% for the placebo group (hazard ratio 0.73 [95% CI 0.52 to 1.03])

Study GS-US-540-5773 in 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 SpO₂ 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.

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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 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, SpO₂ >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. 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 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.**

Remdesivir is a direct acting antiviral drug that inhibits viral RNA synthesis. It is an investigational drug and

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is not currently approved for any indication. Remdesivir has activity in cell culture and animal models against SARSCoV, MERS-CoV, and SARS-CoV-2. Based on review of the topline data from the randomized, double-blinded, placebo-controlled trial conducted by NIAID (NCT04280705) and from the Gilead-sponsored open-label trial that evaluated different durations of remdesivir (NCT04292899), it is reasonable to believe that the known and potential benefits of RDV outweigh the known and potential risks of the drug for the treatment of patients hospitalized with severe COVID-19. (U.S. FDA EUA, 2020b).

National Institute of Health (NIH)

The NIH recently published COVID-19 treatment guidelines which includes discussion on therapeutic options under investigation. At present, no drug has been proven to be safe and effective for treating COVID-19. There are no Food and Drug Administration (FDA)-approved drugs specifically to treat patients with COVID-19. The COVID-19 Treatment Guidelines Panel (the Panel) does not recommend the use of any agents for pre-exposure prophylaxis (PrEP) or for post-exposure prophylaxis (PEP) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outside of the setting of a clinical trial.

The Panel recommends no additional laboratory testing and no specific treatment for persons with suspected or confirmed asymptomatic or presymptomatic SARS-CoV-2 infection. At present, no drug has been proven to be safe and effective for treating COVID-19. There are insufficient data to recommend either for or against the use of any antiviral or immunomodulatory therapy in patients with COVID-19 who have mild, moderate, severe, or critical illness. Although reports have appeared in the medical literature and the lay press claiming successful treatment of patients with COVID-19 with a variety of agents, definitive clinical trial data are needed to identify optimal treatments for this disease.

Recommended clinical management of patients with COVID-19 includes infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilatory support when indicated. As in the management of any disease, treatment decisions ultimately reside with the patient and their health care provider. (NIH, 2020) Included in the guideline is a section for discussion of therapeutic options under investigation that are currently in use by healthcare providers for COVID-19.

Therapies are divided into two broad categories: antivirals, which may target the coronavirus directly, and host modifiers and immune-based therapies, which may influence the immune response to the virus or target the virus. Agents included in the antiviral section at present are as follows: chloroquine, hydroxychloroquine, hydroxychloroquine-azithromycin, remdesivir, and lopinavir-ritonavir. Agents included in the host modifiers and immune-based section at present are as follows: immunoglobulin, interleukin-6 inhibitors (sarilumab, siltuximab, tocilizumab), interleukin-1 inhibitors (anakinra), interferons, and janus kinase inhibitors (baricitinib). At present per the NIH guideline, there is insufficient clinical data to recommend either for or against the use of for all previous mentioned therapies. Specific to chloroquine/hydroxychloroquine, hydroxychloroquine-azithromycin, lopinavir-ritonavir, interferons, and janus kinase inhibitors therapies, the guideline recommends against the use except in the context of a clinical trial. The guideline also include recommendations regarding the use of concomitant medications. These includes: statins, corticosteroids, non-steroidal anti-inflammatory drugs, and certain drugs used to control hypertension (ACE inhibitors, ARBs). Please refer to the guideline for positional statements on the various products. The guidelines will be updated as new data are published in peer-reviewed scientific literature and other authoritative information emerges. (NIH, 2020)

The NIH guidelines were recently updated; the following recommendations were provided:

Remdesivir – Remdesivir is currently approved by the FDA for use in hospitalized patients with COVID-19 and in non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression. Remdesivir has been studied in non-hospitalized patients with mild to moderate COVID-19 who were at high risk of progressing to severe disease. The PINETREE trial showed that 3 consecutive days of intravenous (IV) remdesivir resulted in an 87% relative reduction in the risk of hospitalization or death compared to placebo. Remdesivir is expected to be active against the Omicron variant, although in vitro and in vivo data are currently limited

Recommendations:

1. The Panel recommends using remdesivir 200 mg IV on Day 1, followed by remdesivir 100 mg IV once daily on Days 2 and 3 in those aged ≥ 12 years and weighing ≥ 40 kg; treatment should be initiated as soon as possible and within 7 days of symptom onset (BIIa).
2. Remdesivir should be administered in a setting where severe hypersensitivity reactions, such as anaphylaxis, can be managed. Patients should be monitored during the infusion and observed for at

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least 1 hour after infusion as clinically appropriate.

3. The Panel recommends using remdesivir, dexamethasone, or both drugs together in hospitalized patients who require supplemental oxygen. When remdesivir is used in this setting, it is administered as a once-daily IV infusion for 5 days. There are rare instances when hospital resources are limited and admission to an inpatient unit is not possible for patients who need to initiate supplemental oxygen in the emergency department (ED) or who have increasing supplemental oxygen requirements. In these cases, patients may be discharged from the ED with close monitoring and are often prescribed dexamethasone for up to 10 days. Since remdesivir is often recommended for hospitalized patients with COVID-19 who have similar oxygen needs, clinicians can consider using it in this setting. However, it should be noted that the data on using remdesivir in this situation are limited and administering IV infusions for up to 5 consecutive days can be difficult in the outpatient setting.

The most recent NIH Remdesivir guidelines (July 2023) provided the following recommendations:

Remdesivir - Intravenous remdesivir is approved by the Food and Drug Administration (FDA) for the treatment of COVID-19 in adults and pediatric patients aged ≥ 28 days and weighing ≥ 3 kg. In nonhospitalized patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease, remdesivir should be started within 7 days of symptom onset and administered for 3 days. Hospitalized patients should receive remdesivir for 5 days or until hospital discharge, whichever comes first. The FDA prescribing information for remdesivir indicates that if a patient does not clinically improve, clinicians may extend the treatment course for up to 5 additional days (for a total duration of 10 days).

The recommendations for therapeutic management of nonhospitalized adults with COVID-19 (last updated November 2, 2023) recommends remdesivir second line after ritonavir boosted nirmatrelvir (Paxlovid).

The recommendation for therapeutic management of hospitalized adults with COVID-19 (last updated October 10, 2023) recommends remdesivir first line for patients who do not require supplemental oxygen and are at high risk of progressing to severe COVID-19 and for patients who do require conventional oxygen.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

Coverage will not be authorized for medical necessity usage unless prior authorization request meets ALL criteria defined in the above section. Contraindications to Veklury (remdesivir) include: patients with a history of clinically significant hypersensitivity reactions to Veklury or any components of the product.

OTHER SPECIAL CONSIDERATIONS:

Transaminase elevations have been reported in healthy volunteers who received Veklury. Transaminase elevations have also been reported in patients with COVID-19 who received Veklury. Transaminase elevations have been reported as a clinical feature of COVID-19. FDA label recommends performing hepatic laboratory testing in all patients before starting Veklury and while receiving Veklury as clinically appropriate.

There are TWO different formulations of Veklury:

o Veklury for injection (supplied as 100 mg lyophilized powder in vial) must be reconstituted with Sterile Water for Injection prior to diluting with 0.9% sodium chloride injection.

- The only approved dosage form of Veklury for pediatric patients weighing 1.5 kg to less than 40 kg is

Veklury for injection (supplied as 100 mg lyophilized powder in vial).

o Veklury injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial) must be further diluted in 250 mL of 0.9% sodium chloride injection infusion bag

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device

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code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPDS CODE	DESCRIPTION
J0248	Injection, remdesivir, 1 mg

AVAILABLE DOSAGE FORMS:

Remdesivir SOLR 100MG

Remdesivir SOLR 150MG

Veklury SOLN 100MG/20ML single dose vial

Veklury SOLR 100MG single dose vial

REFERENCES

1. Veklury (remdesivir) for injection, for intravenous use; injection, for intravenous use [prescribing information]. Foster City, CA: Gilead Sciences Inc; December 2024.
2. Gottlieb, R., Vaca, C., Paredes, R., Mera, J., Webb, B., & Perez, G. et al. (2021). Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. *New England Journal Of Medicine*. doi: 10.1056/nejmoa2116846
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Age Restrictions Quantity FDA-Approved Uses Other Special Considerations References	Q1 2025
REVISION- Notable revisions: Required Medical Information Quantity FDA-Approved Uses Background Contraindications/Exclusions/ Discontinuation Other Special Considerations References	Q1 2024
REVISION- Notable revisions: Required Medical Information Drug Class Background Available Dosage Forms References	Q1 2023
REVISION- Notable revisions: Age Restrictions Quantity FDA Approved Uses Compendial Approved Off-Labeled Uses Other Special Considerations References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file