

CADTH DRUG IMPLEMENTATION ADVICE

Remdesivir for Severe Symptoms of COVID-19

(Gilead Sciences Canada Inc.)

Indication: Treatment of COVID-19 in adults and adolescents (12 years and older with a body weight of at least 40 kg) with pneumonia requiring supplemental oxygen

This report was published on October 15, 2020.

To produce this report, CADTH used a modified approach to the selection, appraisal, and synthesis of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

Service Line: CADTH Drug Implementation Advice
Version: Final
Publication Date: October 2020
Report Length: 14 Pages

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Abbreviations

| | |
|-------------|--|
| ACTT | Adaptive COVID-19 Treatment Trial |
| ALT | alanine aminotransferase |
| AST | aspartate aminotransferase |
| CI | confidence interval |
| ECMO | extra-corporeal membrane oxygenation |
| eGFR | estimated glomerular filtration rate |
| FiO2 | fraction of inspired oxygen |
| HR | hazard ratio |
| INR | international normalized ratio |
| IQR | interquartile range |
| NICE | National Institute for Health and Care Excellence |
| PaO2 | oxygen arterial partial pressure |
| PTSD | Post-Traumatic Stress Disorder |
| SaO2 | arterial oxygen saturation |
| SARS | severe acute respiratory syndrome |
| SpO2 | arterial blood oxygen saturation (by pulse-oximetry) |

Introduction and Rationale

Background and Rationale

Remdesivir (Veklury) is the first drug that has been approved, with conditions, by Health Canada for the treatment of coronavirus disease 2019 (COVID-19). The indication is for the treatment of COVID-19 in adults and adolescents (12 years and older with a body weight of at least 40 kg) with pneumonia requiring supplemental oxygen.¹ The drug is administered intravenously and can only be used in health care facilities where patients can be closely monitored.² The product monograph specifies the following related to the approval:

[Remdesivir] has been issued marketing authorization with conditions, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization. For further information for VEKLURY please refer to Health Canada's Notice of Compliance with conditions — drug products website.^{2,3}

The Health Canada recommended dosage of remdesivir in patients 12 years of age and older and weighing 40 kg or greater is:

- day 1 — single loading dose of remdesivir 200 mg given by intravenous infusion
- day 2 onward — 100 mg of remdesivir given once daily by intravenous infusion.

The total duration of treatment should be at least five days and not more than 10 days.

The pandemic associated with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the associated COVID-19 is a health emergency that continues to evolve rapidly. Timely evidence- and expert consensus-informed criteria related to emerging therapies with preliminary clinical data may be useful to support pandemic preparedness and decision-making across the Canadian health system. For this purpose, a panel of clinicians with experience in the treatment of patients with COVID-19 was consulted by CADTH to identify clinical criteria that could help determine which patients would benefit most from treatment with this drug. This work is an extension of CADTH's ongoing assessment of the evidence of using remdesivir for COVID-19;⁴ it is not in relation to a submission by the manufacturer of remdesivir to the CADTH Common Drug Review process.

Objectives

The objective of this report is to provide a summary of clinical expert panel consensus on initiation, discontinuation, and administration criteria for remdesivir in the treatment of patients with COVID-19 who are hospitalized with severe symptoms, defined as those with pneumonia and a need for oxygen as per the indication approved by Health Canada.

Methods

Clinical Evidence Evaluations

A technology review performed by CADTH with a summary and appraisal of the evidence on remdesivir for patients with COVID-19 was used to inform and help panel members develop evidence-informed criteria for identifying patients who are most likely to benefit from the therapy.⁴ The CADTH review is a living document and is updated as new data that meet the inclusion criteria become available.

The literature search for clinical studies was performed by an information specialist using a peer-reviewed search strategy according to the [PRESS Peer Review of Electronic Search Strategies](#) checklist.⁵

Published literature was identified by searching the following bibliographic databases: MEDLINE All (1946–) via Ovid, Embase (1974–) via Ovid, and PubMed. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine’s MeSH (Medical Subject Headings), and keywords. The main search concept was Veklury (remdesivir). Clinical trial registries were searched: the US National Institutes of Health’s ClinicalTrials.gov, WHO’s Organization’s International Clinical Trials Registry Platform via ClinicalTrials.gov, the European Union Clinical Trials Register, and Health Canada’s Clinical Trials Database.

No filters were applied to limit the retrieval by study type. The search was limited to English and French language documents, but was not limited by publication date. Where possible, retrieval was limited to the human population. Conference abstracts were excluded from the search results.

The initial search was completed on September 3, 2020. The search is considered up-to-date as of October 2, 2020.

Grey literature (literature that is not commercially published) was identified by searching relevant websites from the following sections of the *Grey Matters*:⁶ *A Practical Tool For Searching Health-Related Grey Literature* checklist (<https://www.cadth.ca/grey-matters>): Health Technology Assessment Agencies, Health Economics, Clinical Practice Guidelines, Drug and Device Regulatory Approvals, Advisories and Warnings, Clinical Trials Registries, and Databases (Free). Google was used to search for additional internet-based materials. Preprints (unpublished manuscripts) were also searched.

The search strategy is available on request.

Economic Evaluations and Budget Impact Analyses

No economic evaluation or budget impact analyses were conducted for this report. CADTH has economic evaluations in the scoping phase and planning as a potential component for future analyses on this topic.

Patient-Important Outcomes and Perspectives

Outcomes of importance to patients with COVID-19 across the spectrum of disease were identified by CADTH in a search of the literature.

A survey using abbreviated Core Outcome Measures in Effectiveness Trials methods to obtain patient-important outcomes was identified and selected.⁷ Based on a survey of 9,289 participants from 111 countries (776 people with COVID-19 or family members, 4,882 health professionals, and 3,631 members of the public), the four outcomes of highest priority were: mortality, respiratory failure, pneumonia, and organ failure.

Survey respondents gave higher priority to outcomes that were seen as a threat to survival and given the uncertain trajectory and prognosis of COVID-19, participants gave higher priority to outcomes related to disease progression. Severe outcomes that required isolation or admission to intensive care units or invasive interventions were distressing and “could be linked to longer-term issues such as PTSD [post-traumatic stress disorder].” Symptoms that “lingered” and impaired quality of life (e.g., shortness of breath) were given higher priority.

For patients, the high prioritization of impact on family, depression, and anxiety reflected angst about isolation and profound guilt of infecting others. Anxiety was also rated high because it exacerbated symptoms — “this uncertainty causes anxiety and makes breathing harder.”

A published systematic review from the BMJ Rapid Recommendations panel on drugs for the treatment of COVID-19 included input from unconflicted clinical experts and patient-partners without declared conflicts of interest to identify outcomes of highest importance to patients.⁸ The panel rated outcomes on a scale from 1 to 9 (9 being the most important) and included only those outcomes with a score of at least 7 as rated by any panel member. The outcomes that were identified as most important to patients were: mortality, mechanical ventilation, adverse events leading to discontinuation, viral clearance, duration of hospital stay, intensive care unit length of stay, time to symptom resolution or clinical improvement, and time to viral clearance.

Implementation Advice Panel

CADTH convened a panel of five clinical experts with experience in the diagnosis and treatment of patients with COVID-19. The clinicians involved in the panel included respirologists, intensivists, and infectious disease specialists. The panel also included an ethicist. The panel meeting was held on September 9, 2020 to discuss appropriate initiation, renewal, and administration criteria for remdesivir in patients with severe COVID-19 symptoms (those with pneumonia requiring supplemental oxygen as defined by the indication approved by Health Canada).

Following the panel meeting, CADTH staff prepared a summary of the input provided by the panel, with further input from the panellists. The manufacturer of remdesivir was given the opportunity to comment on the draft document.

The clinical criteria in Table 1 may be updated as evidence for the use of remdesivir evolves.

Clinical Evidence

Key Findings From Clinical Evaluations

CADTH has recently evaluated the clinical evidence on the potential benefits and harms of remdesivir⁴ where four key studies of efficacy were available.⁹⁻¹² The updated literature search confirmed that one completed trial was published in full,¹² another trial (Adaptive COVID-19 Treatment Trial [ACTT])¹¹ had published preliminary data,¹³ with final results published recently,¹⁴ and one ongoing manufacturer-sponsored trial (GS-US-540-5773) that compared remdesivir for five versus 10 days in patients 12 years and older who were hospitalized with severe symptoms of COVID-19⁹ has also published preliminary results.¹⁵ The GS-US-540-5774^{10,16} is another manufacturer-sponsored trial that was ongoing at the time of the CADTH Technology Review but has since been published,¹⁶ and evaluated patients with moderate symptoms of COVID-19; its population is out of scope for this assessment.

The two available trials relevant to this report, Wang et al.¹² and ACTT^{11,13,14}, are phase III, randomized, double-blind, placebo-controlled trials that enrolled patients hospitalized with COVID-19 and pneumonia who required supplemental oxygen. Wang et al. was stopped early and did not reach its planned power, recruiting 237 patients with severe disease, of whom 16.1% were critically ill at baseline. The ACTT-1 trial reported on 1,062 patients (from

13 countries in North America, Europe, and Asia) with most of the patients (85%) having severe disease (defined as one or more of the following: those who required supplemental oxygen via mechanical ventilation or other method of administration, had oxygen saturation as measured by pulse oximetry [Spo₂] of 94% or lower while they were breathing ambient air, or if their respiratory rate was 24 breaths per minute or higher). Patients in both trials were randomized approximately nine to 11 days after initial symptom onset with a mean age between 58 and 65 years.

GS-US-540-5773 was a manufacturer-conducted, open-label, randomized trial that compared remdesivir treatment regimens of different duration (remdesivir plus standard of care for either a five-day or a 10-day treatment regimen) in patients diagnosed with severe COVID-19. The trial was split into two parts. Part A enrolled only patients who were not mechanically ventilated; whereas, Part B enrolled patients receiving mechanical ventilation. Only data from Part A were available at the time of drafting the technology review.

In the study by Wang et al. the median time to clinical improvement (with clinical improvement defined as a two-point improvement on a six-point ordinal scale) was 21 days (interquartile range [IQR] = 13.0 to 28.0) with remdesivir and 23 days (IQR = 15.0 to 28.0) with placebo (hazard ratio [HR] = 1.23; 95% confidence interval [CI], 0.87 to 1.75; P = 0.24). At day 28, 65% (103 out of 158) patients on remdesivir were deemed clinically improved compared to 58% (46 out of 78) in the placebo group (risk difference = 7.5%, 95% CI, -5.7 to 20.7). At day 28, 14% (22 out of 158) patients on remdesivir had died compared with 13% (10 out of 78) patients on placebo (risk difference = 1.1; 95% CI, -8.1 to 10.3). There was also no statistically significant difference in the median duration of invasive mechanical ventilation (difference in days by Hodges-Lehmann estimation equals fewer than four days, 95% CI, -14.0 to 2.0), duration of oxygen support (-2.0 days; 95% CI, -6.0 to 1.0), and days of hospitalization (0.0; 95% CI, -4.0 to 4.0). The study suggested that remdesivir results in little to no difference versus placebo in the outcomes that were measured in the study, potentially owing to important limitations with the design and conduct of the trial (see Key Limitations of the Clinical Evidence section).

From the ACTT trial, the median time to recovery was 10 days in the remdesivir group versus 15 days in the placebo group (rate ratio = 1.29; 95% CI, 1.12 to 1.49; P < 0.001). Mortality at day 15 was 6.7% and 11.9% in the remdesivir and placebo groups, respectively (HR = 0.55; 95% CI, 0.36 to 0.83). The estimates of mortality at day 29 were 11.4% and 15.2% in the remdesivir and placebo groups, respectively (HR = 0.73; 95% CI, 0.52 to 1.03). The odds of improvement in clinical status on the eight-point ordinal scale was higher with remdesivir than with placebo at day 15 (odds ratio for improvement = 1.5; 95% CI, 1.2 to 1.9).

No statistical difference was found between the remdesivir five-day and 10-day treatment regimens in the primary outcome of clinical status at day 14 after adjusting for clinical status at baseline in GS-US-540-5773 (odds ratio = 0.79; 95% CI, 0.61 to 1.01; P = 0.14). The median time to recovery was 10 days in the five-day remdesivir group and 11 days in the 10-day remdesivir group (HR = 0.81; 95% CI, 0.64 to 1.04). Mortality at day 14 was 8% in the five-day treatment group and 11% in the 10-day treatment group. The latter two outcomes were exploratory in the trial.

The percentage of patients who experienced any adverse events were similar in the remdesivir and placebo groups based on the Wang et al. study, but the percentage of patients who experienced a serious adverse event was higher in the placebo group than the remdesivir group in both the Wang et al. and ACTT studies. Adverse effects most commonly

reported that are potentially related to remdesivir are increases in liver enzymes and acute kidney injury.

Key Limitations of the Clinical Evidence

A full description of the limitations of the evidence from clinical trials for remdesivir may be found in the CADTH technology summary and appraisal.⁴

Overall, the evidence for the benefit of remdesivir from the randomized trials is of low certainty and with limitations that preclude drawing conclusions with confidence in the magnitude of the treatment effect estimates due to imprecision. There are concerns regarding the sample sizes of the studies, most notably the Wang et al. study was terminated early when the epidemic of COVID-19 was brought under control in China and no additional patients could be enrolled. The trial data were analyzed when 237 patients had been randomized into the study instead of the planned 457 patients. The studies were also seemingly under powered to examine the treatment effects of remdesivir in subgroups, when these subanalyses were performed. Additional limitations for the subgroup analyses from the studies included that not all subgroup analyses were pre-specified, few of the subgroups were stratification factors at randomization and it is unclear if randomization was maintained for the subanalyses, as well there was no control of the type I error rate for the subgroup analyses.

Study 5773 was designed to compare two dosing regimens of remdesivir, but did not include a control arm (i.e., a comparison to standard care), which makes it difficult to interpret the clinical efficacy outcomes of the trial. While both treatment durations appeared to have similar clinical efficacy, it remains unclear whether either the five-day or 10-day treatment regimen improved clinical status, reduced the time to recovery or to clinical improvement, or improved mortality beyond standard of care in patients with severe COVID-19.

Safety data were limited too as follow-up was not long enough to provide definitive conclusions regarding adverse events associated with remdesivir in the studied populations.

The CADTH technology summary and appraisal concluded that the current evidence is insufficient to determine which patients are more likely to benefit from remdesivir and if a shorter course (five days) of remdesivir offers the same benefits as a longer course of treatment. Additional trial results are required to determine the potential place in therapy of remdesivir. Other published reviews of treatments for patients with COVID-19 have drawn similar conclusions.^{8,17}

Implementation Advice Panel

Initiation, discontinuation, and administration or prescribing criteria and conditions for remdesivir for the treatment of COVID-19 are shown in Table 1.

A summary of the relevant clinical panel input is also provided.

The criteria on the clinical value of remdesivir were deliberated on in the context of the ongoing public health emergency of the COVID-19 pandemic. The criteria reflect the panel's conclusions based on the best available evidence for the treatment effects of remdesivir in the Health Canada indicated population, and their opinions based on clinical expertise in the diagnosis and management of COVID-19. The panel also discussed ethical considerations for the judicious use of remdesivir, particularly in scenarios of high demand for treatment.

Treatment Goals

The panel agreed that the most important goals for measuring the effects of therapies for COVID-19, including remdesivir, are a decrease in mortality, decreased time on life support (number of days on ventilator and/or extra-corporeal membrane oxygenation [ECMO]), improved health-related quality of life, improved function, reduced time in hospital, a reduction in long-term morbidity associated with COVID-19, and recovery. The panel also noted that harms associated with such a treatment should be minimized and ideally the treatment would be cost-effective.

The clinical goals described by the panel are well-aligned with the previously described patient-important outcomes and perspectives.

Place in Therapy

The panel discussed their concerns related to the current state of the evidence for remdesivir for the treatment of patients with COVID-19, citing that available results from randomized trials do not yet provide high certainty for the effectiveness of remdesivir on patient-important outcomes. The lack of comparative data with other drugs used for the treatment of COVID-19 also makes it difficult to estimate the magnitude of the clinical benefit associated with remdesivir. The panel noted that the approval of remdesivir by Health Canada was based on the condition of additional clinical data being gathered to support the efficacy of the drug. Furthermore, the cost-effectiveness of remdesivir is unknown because of the limitations in the clinical data and limited publicly available economic analyses. Therefore, the panel was of the opinion that use of remdesivir in patients with COVID-19 who have pneumonia and require supplemental oxygen should be in the context of clinical trials to gather more data on its efficacy and harms.

At the time of the panel meeting, there is limited publicly available criteria from guidelines or other evidence-informed guidance for targeting the use of remdesivir to patients who are most likely to benefit from the drug. Currently available criteria from other health agencies highlighted difficulties specifying such criteria because of the aforementioned limitations with the evidence for the efficacy of remdesivir.¹⁷⁻¹⁹

Initiation criteria

The panel agreed that — if remdesivir is to be used — it should be used with consideration of those patients who responded best in the randomized trials to date, this is, patients hospitalized for COVID-19 with pneumonia, who required supplemental oxygen. The

discussion of the subgroup results agreed with the CADTH assessment that the analyses of different populations were limited and exploratory in nature, making it difficult to identify subgroups of patients most likely to benefit from treatment with remdesivir.

The panel noted that the Wang et al., ACTT, and 5773 studies predominately enrolled patients who required low-flow supplemental oxygen (approximately 82%, 40%, and 55% respectively). There is uncertainty whether remdesivir provides clinical benefit in patients who required supplemental oxygen delivered through a high-flow device, invasive mechanical ventilation, or ECMO because of the smaller percentage of these subgroups of patients enrolled in the studies. The panel also expressed concerns regarding variability and evolving definitions of disease severity. It was noted that most patients (approximately 89%) in ACTT were considered to have severe COVID-19 according to the study criteria, which align with the National Institute of Health definitions based on oxygen saturation. The National Institute of Health defines severe illness as: "Individuals who have respiratory frequency > 30 breaths per minute, $SaO_2 \leq 93\%$ on room air at sea level, ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO_2/FiO_2) < 300, or lung infiltrates > 50%."²⁰ Therefore, it was agreed that the criteria used in the studies to define severity (pneumonia requiring supplemental oxygen [$SpO_2 \leq 94\%$ on room air, or respiratory rate ≥ 24 breaths/minute]) are similar to the ones that would be appropriate for identifying patients to receive remdesivir. The experts also noted that, although pregnant or breastfeeding women were excluded from the trials, these patients would not necessarily be excluded from receiving remdesivir in practice.

The panel discussed the duration of treatment with remdesivir and noted that the magnitude of the effectiveness of a five-day treatment appears similar to that of a 10-day treatment. Therefore, a five-day course would be the standard duration to begin therapy in most of the patients. If no improvement is achieved after five days (per the previously mentioned treatment goals), then remdesivir treatment could be extended to a maximum of 10 days, depending on the clinical judgment of the multi-disciplinary team and considering availability of the drug. The panel emphasized that the suggestion to treat for five days is based on evidence with low certainty of benefit; the optimal duration of treatment with remdesivir for all patients with COVID-19 is unknown.

The median time from onset of COVID-19 symptoms to initiating treatment with remdesivir in the three trials was approximately 10 days (medians ranged from eight to 11 days; interquartile ranges from five to 13 days). However, the panel agreed that initiation of any antiviral, not just remdesivir, should occur as early as possible. It is unclear what magnitude of benefit, if any, would be achieved with starting remdesivir in patients whose symptoms have persisted for longer than the time from symptom onset to treatment initiation reported in the trials.

As well, the current evidence is unclear as to whether there is benefit in having patients receive other therapies for COVID-19 before remdesivir. Therefore, requiring that patients receive other drugs before initiating treatment with remdesivir would not be appropriate at this time. Also, due to a lack of evidence from well-controlled randomized trials, the panel could not determine how remdesivir should be used concomitantly with other drugs, such as dexamethasone.

Discontinuation criteria

The panel agreed with the criteria for stopping treatment with remdesivir that has been described by other jurisdictions.^{17,19} Remdesivir should be discontinued in patients who

develop an increase in liver enzymes (alanine aminotransferase [ALT] or aspartate aminotransferase [AST] ≥ 5 times the upper limit of normal during treatment with remdesivir, ALT or AST elevation with increasing conjugated bilirubin, alkaline phosphatase, international normalized ration [INR], or other signs and symptoms of liver inflammation) and decreased kidney function (an estimated glomerular filtration rate [eGFR] less than 30 mL/min/1.73 m²). Experts also suggested stopping treatment as soon as its effect is thought to no longer be relevant; that is, either as soon as the patient is clinically well or if by day five it is not meeting the treatment goals (Table 1).

Continuation of treatment depends on whether treatment goals have been met and the availability of remdesivir. If patients require continuation after five days of treatment, it should be based on assessment by a multi-disciplinary care team, then the maximum treatment duration will be 10 days.

Prescribing conditions

The panel generally agreed, as per the product monograph, that the hospital setting with proper facilities for the administration of the drug and monitoring is the appropriate treatment setting. They noted that in rural areas administration of remdesivir and monitoring its effects may need to be done in whatever available health care facilities with the staff and resources to support treatment with remdesivir are available. In such situations, use of remdesivir should be done in consultation with specialists from tertiary centres.

Similarly, the experts agreed that the treating multi-disciplinary team would be the most appropriate to administer remdesivir, given appropriate guidance on the patients to use the drug in.

Table 1: Summary of Initiation, Discontinuation, and Administration Criteria for Remdesivir

| Initiation criteria |
|---|
| <p>Remdesivir may be used in hospitalized patients if all of the following criteria are met:</p> <ul style="list-style-type: none"> • patients are 12 years and older and weigh at least 40 kg • patients have laboratory-confirmed SARS-CoV-2 infection and diagnosis of COVID-19 • patients have pneumonia requiring supplemental oxygen (SpO₂ \leq 94% on room air, or respiratory rate \geq 24 breaths/minute) • patients have eGFR levels greater than or equal to 30 mL/min/1.73 m² • patients have ALT (or AST) levels below five times the upper limit of normal at baseline. <p>Remdesivir may be considered for use in patients who require supplemental oxygen delivered through a high-flow device, invasive mechanical ventilation, or ECMO; however, the evidence to support use in these patients is highly uncertain. In times of limited supply^a, remdesivir should be prioritized for patients requiring supplemental low-flow oxygen.</p> <p>Determining the balance of benefits to harms for the use of remdesivir in pregnant or breastfeeding patients should be made in collaboration between the multi-disciplinary care team and the patient or patient representative.</p> <p>Treatment should not be started if the patient is expected to be discharged from hospital in the next 72 hours.</p> |
| Discontinuation criteria |
| <p>Continuation of treatment should be assessed at day five.</p> <ul style="list-style-type: none"> • Continuation of treatment depends on whether treatment goals^b have been met and the availability^a of remdesivir. • If patients require continuation after five days of treatment based on assessment by the multi-disciplinary care team, then the maximum total treatment period cannot exceed 10 days. <p>Treatment with remdesivir may be discontinued before day five if treatment goals have been met.</p> <p>Treatment with remdesivir should be discontinued in patients for any of the following:</p> |

Discontinuation criteria (cont'd)

- ALT (or AST) greater than or equal to five times the upper limit of normal during treatment with remdesivir (remdesivir may be restarted when ALT [or AST] is < 5 times the upper limit of normal per the product monograph)
- ALT (or AST) elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR, or other signs or symptoms of liver toxicity
- eGFR lower than 30 mL/min
- signs or symptoms of serious hypersensitivity reaction, or another serious adverse event related to remdesivir.

Treatment with remdesivir should be discontinued when the patient is being discharged from hospital.

Prescribing conditions

Remdesivir should be prescribed and patients monitored by a multi-disciplinary team. A multi-disciplinary team should ideally include representation from a minimum of three clinicians with appropriate expertise. Suggested areas of clinical expertise include respiratory medicine, critical care, general medicine, or infectious diseases.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; COVID-19 = coronavirus disease; ECMO = extra-corporeal membrane oxygenation; eGFR = estimated glomerular filtration rate; INR = international normalized ratio; SpO₂ = arterial blood oxygen saturation (by pulse-oximetry).

^a After the approval of remdesivir by Health Canada and other agencies worldwide, concerns about scarcity of the medication have been noticed, and measures are being established by the Canadian authorities due to the possible exacerbations of existing shortages, increased demand, stockpiling, misuse, and/or supply chain disruption.²¹ The manufacturer of remdesivir and the Public Health Agency of Canada have recently stated that remdesivir will be available and will meet demand in Canada and globally.²²

^b Treatment goals should be established by a multi-disciplinary care team and the patient or patient representative. These may include: prevention of death, prevention of intubation and/or other advanced life support measures, resolution of COVID-19 symptoms, reduced duration of symptoms, improved health-related quality of life, and/or improved ability to engage in daily activities.

Conclusions

Currently available best evidence suggests that remdesivir may lead to faster recovery in some patients hospitalized with pneumonia and requiring supplemental oxygen. However, the magnitude of benefits is relatively small, and it is unclear that this finding meets treatment goals important to patients. There is, as of yet, no evidence that remdesivir improves important clinical outcomes such as mortality.

It is stressed that the evidence base for these criteria and conditions was in general preliminary and of low certainty. Additional data from large, well-designed randomized trials are needed to obtain more confidence in the magnitude of the benefits of treatment with remdesivir.

The provided criteria will need to be updated as evidence for the use of remdesivir and the treatment of COVID-19 evolve.

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