Specific Care Question
What are the risks and benefits of treatment with remdesivir in children with COVID-19?

Recommendations from the COVID-19 Clinical Pathway Committee

The COVID-19 Clinical Pathway Committee **recommends** remdesivir for hospitalized patients with severe illness, excluding those under 2 years of age with bronchiolitis. However, it **does not** recommend remdesivir for patients in the ambulatory setting with mild to moderate disease or those hospitalized with mild to moderate illness without risk for progressing.

This leaves several groups of patients for whom there is insufficient evidence to provide a recommendation for or against remdesivir:

1. Ambulatory patients with a risk for progression to severe disease.
2. Hospitalized patients with mild to moderate illness with a risk for progression to severe disease.
3. Hospitalized patients under 2 years of age with bronchiolitis.

For these patients, the Clinical Pathway Committee recommends applying the following summary of evidence and employing shared decision-making with the patient and family.

Rationale for Question Asked

Remdesivir, a ribonucleic acid (RNA) polymerase inhibitor, disrupts translation in RNA viruses like SARS-CoV-1 and SARS-CoV-2. In May 2020, the FDA issued an emergency use authorization (EUA) for remdesivir in patients aged 12 and older, weighing at least 40 kg, requiring hospitalization for COVID-19. In February 2022, the Infectious Diseases Society of America (IDSA) established guidelines based on adult studies, recommending remdesivir for patients (ambulatory or hospitalized) with mild to moderate illness at high risk for progression to severe disease and those hospitalized with severe disease (Bhimraj et al., 2022). However, the IDSA guidelines did not provide pediatric-specific recommendations for remdesivir treatment. It was not until April 2022 that the FDA approved its use in patients aged 28 days and older, weighing at least 3 kg. Therefore, treatment decisions are based primarily on adult studies.

Study characteristics. The search for suitable studies was completed on November 13, 2024. A. Melanson and K. Berg reviewed the 82 titles and/or abstracts found in the search and identified one guideline and 12 single studies believed to answer the question. After an in-depth review of one guideline and single studies, 12 answered the question(s).

Overview of Evidence

Ambulatory Setting

Studies of remdesivir's efficacy and safety for patients with COVID-19 in the outpatient setting are limited. Gottlieb et al. (2021) conducted an RCT comparing treatment with three days of remdesivir to placebo in the ambulatory setting, which included patients (N = 562) who had risk factors for progression to severe disease. While some pediatric patients ≥ 12 years were included, the mean age was 50. Results of the study showed that treatment with remdesivir reduced hospitalizations (HR = 0.13, 95% CI [0.03, 0.59], p = .008) and COVID-19-related medical visits (HR = 0.19, 95% CI [0.07-0.56], p = .002) with no adverse drug events reported (Gottlieb et al., 2021). Referencing only this primarily adult-based study, the IDSA practice guideline recommended remdesivir for ambulatory patients with risk for progression to severe disease (conditional recommendation, low certainty of evidence), also stating that "patient-specific factors (e.g., patient age, symptom duration, renal function, drug interactions), product availability, institutional capacity, and infrastructure should drive decision-making regarding choice of agent." Gottlieb et al. and the IDSA guideline did not provide pediatric-specific recommendations for patients in the ambulatory setting. A review of the literature since the IDSA guideline publication did not yield pediatric studies that address this question. In summary, one must consider feasibility, patient comfort, cost (including non-monetary), and the values of the patient and family when determining the value of this daily intravenous medication.

Inpatient Setting

Efficacy

Most studies on the efficacy and safety of remdesivir in the inpatient setting have excluded pediatric patients. Two randomized, open-label trials included patients as young as 12 years of age (Goldman et al., 2020; Spinner et al., 2020). Spinner et al. (2020) included hospitalized patients with severe COVID-19 and evidence of pneumonia (*N* = 596) who were randomized to a 10-day course of remdesivir, a 5-day course of remdesivir, or standard care. Greater clinical improvement was reported in the 5-day group, but there was no difference in the 10-day versus standard care groups (Spinner et al., 2020). Goldman et al. (2020) included hospitalized patients with COVID-19, hypoxia, and pneumonia and randomly assigned them to remdesivir for 5 or 10 days (*N* = 397) without a control arm. There was no difference in clinical improvement between the 5- and 10-day groups (Goldman et al., 2020). Neither study provided a sub-analysis specifically evaluating patients who are 12 years old or older. The IDSA guideline cited these two studies but did not provide a recommendation for children (Bhimraj et al., 2022).

Since the IDSA guideline section on remdesivir was last reviewed (2/2022), four studies have reported on the efficacy of remdesivir for children in the inpatient setting (Kautsch et al., 2023; Minotti et al., 2023; Romani et al., 2024; Shoji et al., 2023). Details on study design, outcomes, and limitations can be found in **Table 1.**

- According to Kautsch et al. (2023), remdesivir did not reduce the mortality rate in children with severe disease, as shown in **Table 1**. However, in patients with mild disease and known risk factors for progression, the drug significantly reduced progression to severe disease. Of the 48 patients with asymptomatic to moderate disease that received remdesivir, none progressed to severe or critical disease compared to 13 patients not treated with remdesivir [10 progressed to critical and 3 progressed to severe disease] (Kautsch et al., 2023).
- Minotti et al. (2023) reported no differences in the efficacy of remdesivir as compared to monoclonal antibodies for the early treatment of COVID-19 in children with significant comorbidities.
- In the study by Romani et al. (2024), results were inconclusive regarding the effectiveness of remdesivir. There was no statistically significant difference in recovery without sequelae (Remdesivir > 5 days, 71% vs. Remdesivir ≤ 5 days, 96%; p = .101).
- In a propensity score-matched cohort study, Shoji et al. (2023) demonstrated that, in hospitalized children with COVID-19, the rate of patients achieving absence of fever on day four was higher in the remdesivir group than in the non-remdesivir group but was not statistically different (86.7% vs 73.3%, p = .333). Due to the small sample size, the researchers were unable to evaluate the impact on mortality.

These studies had several limitations. There were variances in how patients were randomized. With the exception of the propensity-score-matched cohort study by Shoji et al. (2023), treatment groups differed (remdesivir vs. no remdesivir, remdesivir vs. monoclonal antibodies, ≤ 5 days vs. > 5 days). Important differences in the groups included age, comorbid conditions, severity of illness, and receipt of other medications for COVID-19. Indications for treatment with remdesivir varied amongst and within studies. Even when the decision to treat was based on disease severity, definitions of severity classifications varied amongst studies.

Safety

Studies of adverse events related to remdesivir treatment are also limited. In adult patients, a 5-day course of remdesivir may be associated with fewer adverse drug events than a 10-day course (*RR* = 0.61, 95% CI [0.44, 0.85], low CoE and *RR* = 0.44, 95% CI [0.21, 0.95], low CoE, respectively), but the certainty of evidence is low due to increased severity of disease in those receiving 10 days (Goldman et al., 2020). Prior to the IDSA guideline, one study included children admitted with severe COVID-19 who received remdesivir under compassionate use (*N*=77) and reported an increase in AST and ALT, 55% and 48% of patients, respectively (Goldman et al., 2021).

Since the IDSA's most recent review (2/2022), six studies have evaluated the safety of remdesivir in children hospitalized with COVID-19 (Ahmed et al., 2022; Jinda et al., 2022; Manabe et al., 2022; Player et al., 2024; Romani et al., 2024; Samuel et al., 2023). Details on study design, outcomes, and limitations can be found in **Table 1**.

- Ahmed et al. (2022) reported on a phase 2/3, open-label trial to evaluate remdesivir dosing and adverse events. Included were children aged 28 days to 17 years who were hospitalized for COVID-19 (*N* = 53). All but one patient had a pre-existing chronic medical condition. All patients received up to 10 days of remdesivir (median duration of 5 days) with the following dosing: Patients ≥ 40kg, 200mg - day 1, then 100 mg/day; patients ≥ 28 days and ≥ 3kg to < 40kg, 5 mg/kg day 1, then 2.5 mg/kg/day. With this dosing, pharmacokinetic evaluation demonstrated drug exposure similar to that achieved with adult dosing. Drug-related adverse events, such as hypomagnesemia, bradycardia, hypertension, hyperglycemia, and acute kidney injury, were reported in eight patients, though none were classified as severe (Ahmed et al., 2022).

Several retrospective, single-arm studies reported the incidence of adverse drug events following remdesivir treatment of children hospitalized with COVID-19.

- Jinda et al. (2022) identified AST and/or ALT elevation in 12/66 children. Transaminase elevation was associated with comorbid conditions, longer duration of remdesivir course (7.5 days vs. 3 days), and more frequent acetaminophen use.
- Player et al. (2024) reported that most abnormalities following remdesivir were transient. Of 180 included patients, creatinine elevation occurred in 28 patients and was associated with severity of COVID-19 illness. It remained elevated only in those with known chronic kidney disease. Transaminase elevation occurred in 60 patients and was more common in older patients (mean 13.3 years). Of note, the median duration of therapy was only one day (Player et al., 2024).
- Transient elevation in transaminases was also shared by Manabe et al. (2022) with 4/20 patients who received remdesivir for 3-10 days, having subsequent elevation in AST or ALT.
- Out of 50 patients included in a study by Romani et al. (2024), AST and ALT elevations occurred in 13 and 16 patients, respectively. There was no difference in the frequency of transaminase elevation in patients treated with ≤ 5 days versus > 5 days of remdesivir (Romani et al., 2024).
- In contrast, Samuel et al. (2023) reported no renal or hepatic toxicity among 48 included patients but did report bradycardia (12.5%) and hypertension (54.2%) following remdesivir administration. Bradycardia was associated with patient age, specifically those > 12 years (Samuel et al., 2023).

These studies have notable limitations. They did not include a comparison group without remdesivir treatment. Few patients had baseline labs obtained before remdesivir treatment, and not all patients obtained post-treatment labs. With the majority of patients having underlying comorbidities, laboratory abnormalities and other adverse events could have been related to these conditions rather than remdesivir. Similarly, some of the reported lab abnormalities are known to occur with COVID-19 disease. Finally, patients received other medications besides remdesivir during the same hospital stay, complicating the analysis of adverse drug events.

Overall, while remdesivir shows some adverse events in children, these are generally consistent with those seen in adults and are often transient or linked to pre-existing conditions.

Identification of Studies

Search Strategy and Results

((("Outpatients"[Mesh] OR "Outpatient Clinics, Hospital"[Mesh] OR "Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR "outpatient" OR "outpatient department" OR "outpatient care" OR "ambulatory care" OR "urgent care") AND remdesivir) AND ("Child"[MeSH Terms] OR "Adolescent"[MeSH Terms] OR "Pediatrics"[MeSH Terms] OR "Infant"[MeSH Terms] OR "pediatri*"[All Fields] OR "Child"[All Fields] OR "children"[All Fields] OR "Infant"[All Fields] OR "Adolescent"[All Fields] OR "adolescence"[All Fields] OR "Infant"[MeSH Terms] OR "Child"[MeSH Terms] OR "Adolescent"[MeSH Terms] OR "infant, newborn"[MeSH Terms] OR "Infant"[MeSH Terms] OR "Infant"[MeSH Terms:noexp] OR "Child"[MeSH

Terms:noexp] OR "child, preschool"[MeSH Terms] OR adolescent[Filter] OR allchild[Filter] OR allinfant[Filter] OR child[Filter] OR infant[Filter] OR newborn[Filter] OR preschoolchild[Filter]). Inpatient was added to an additional search to identify studies specific to hospitalized patients.
Search Dates: 2022-Current
Records identified through database searching *n* = 0
Additional records identified through other sources *n* = 9

Question Originator
The COVID-19 Clinical Pathway Committee members
Findings from this review were presented on January 29, 2025.
Medical Librarian Responsible for the Search Strategy
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Table 1
COVID-19 in Children: Evidence for Treatment with Remdesivir (RDV)

Author (year)	Study Type	Country	Population	Participants	Outcomes			Limitations of the Study
					LOS	Mortality	Adverse Drug Events	
Ahmed et al., 2022	Observational Prospective	United States, Italy, Spain, and the United Kingdom	Hospitalized patients with COVID-19 Age range: 28 days to 17 years (median age, 7 years)	*N* = 53 98% with comorbidities (most commonly obesity, asthma, and cardiac)	Median LOS: 7 days	Mortality: *n* = 3 (6%)	• Any adverse drug event: *n* = 8 (none classified as serious) • Elevated AST and ALT: *n* = 2 (both with known elevations prior to RDV)	• Single-arm study with small numbers of participants in each cohort; no comparison • Most participants did not have labs pre- and post-treatment for comparison
Jinda et al., 2022	Case-control Retrospective	Japan	Hospitalized patients with COVID-19 Age range: < 18 years (median age, 10 years)	*N* = 66 94% with comorbidities (most commonly neurologic, cardiac, and respiratory)	Not reported	None reported	• Elevated AST and/or ALT: *n* = 12 (of those with repeat levels obtained, all improved)	• Retrospective • Single-arm study with small numbers of participants; no comparison • Single center • Most participants did not have labs pre- and post-treatment for comparison

Kautsch et al., 2023	Cohort, Retro-spective	Poland	Hospitalized patients with COVID-19 Age range: 1 week to 18 years (median age, 4 years)	*N* = 328 • RDV, *n* = 64 • No RDV, *n* = 264 79% with comorbidities, including 36% with immunodeficiency	Median LOS: • RDV, 12 days • No RDV, 7 days	Mortality: • RDV, 3 (4.69%) • No RDV, 2 (0.76%) • *P* = .02	• Moderately elevated AST and/or ALT: *n* = 4 (each received RDV) • No other observed side effects, including no renal toxicity or bradycardia	• Retrospective • Non-randomized; treatment and non-treatment groups differed by comorbidities and severity of illness • Small cohort treated with RDV • Single center
Manabe et al., 2022	Case-series, Retro-spective	Japan	Hospitalized patients with COVID-19 Age range: 5 months to 19 years (median age, 2 years)	*N* = 20 85% with comorbidities (most commonly respiratory, cardiac, and neurologic)	Median LOS: 7 days	None reported	• Mildly elevated AST and/or ALT: *n* = 4 • Other lab abnormalities: *n* = 1 (neutropenia and hypokalemia) • No renal toxicity or bradycardia	• Retrospective • Single-arm study with small numbers of participants; no comparison • Single center • Patients who already had elevated creatinine or ALT were excluded
Minotti et al., 2023	Observa-tional, Retro-spective	Italy	Hospitalized patients with COVID-19 and treated with bamlanivimab-etesevimab, molnupinavir, nimatrelvir-ritonavir, remdesivir, or sotrovimab Age range: <18 years (median	*N* = 32 *n* = 7 treated with RDV All with comorbidities • 69% hematology/oncology • 12% transplant • 19% other	Not reported	Mortality in the group treated with RDV: *n* = 1 (reported to be due to other causes)	• Adverse drug events specific to patients treated with RDV are not reported • No severe adverse drug events	• Retrospective • Small number total and treated with RDV • Non-randomized; treatment groups differed by comorbidities and severity of illness • Many patients received more than one therapy, including monoclonal antibodies • Single center

			age, 8.5 years)					
Player et al., 2024	Observa-tional, Retro-spective	United States	Hospitalized patients with COVID-19 and treated with at least 1 dose of RDV Age range: <22 years (median age, 10.5 years)	*N* = 180 79% with comorbidities (most commonly chronic lung disease, neurodevelop mental, genetic, technology dependence, overweight/o besity	Not reported	Mortality: *n* = 3	• Elevated creatinine: *n* = 28 (transient in those without underlying renal disease) • Elevated AST and/or ALT: *n* = 60 (42/60 had elevation prior to RDV) (transient in all but 2) • Urticaria: *n* = 1	• Retrospective • Single-arm study; no comparison group • Single center • Not all patients had baseline labs obtained
Romani et al., 2024	Observa-tional, Retro-spective	Italy	Hospitalized patients with COVID-19 and treated with RDV (median duration of treatment not reported) Age range: <18 years (median age, 12.8 years)	*N* = 50 • RDV > 5 days, *n* = 9 • RDV ≤ 5 days, *n* = 32 78% with at least one comorbidity (most commonly obesity)	Median LOS: • 12 days Median PICU stay: • 15 days (34% of pts were admitted to PICU)	Mortality: • RDV > *5 days, n* = 0 • RDV ≤ 5 days, *n* = 1	Bradycardia: • RDV > 5 days, *n* = 0 • RDV ≤ 5 days, *n* = 2 Rash: • RDV > 5 days, *n* = 0 • RDV ≤ 5 days, *n* = 3 No renal toxicity Elevated AST: • *n* = 13 Elevated ALT: • *n* = 16 **RDV group not identified for AST/ALT*	• Retrospective • No control arm without RDV treatment • Many patients received more than one therapy, including systemic steroids
Samuel et al., 2023	Observa-tional, Retro-spective	United States	Hospitalized patients with COVID-19 and treated with RDV	*N* = 48 55% with comorbidities (most commonly obesity,	Median LOS: 4.5 days Median PICU stay: 3 days	Mortality: *n* = 1 (seven months after hospitalization)	• Bradycardia, 12.5% • Hypertension, 54.2% • No hepatic or renal toxicity	• Retrospective • Single-arm study with small number of participants; no comparison • Single center • Multiple confounding factors, including

			Age range: ≤18 years (median age, 12.5 years)	pulmonary, and cardiac) 15% were immuno-compromised				concomitant treatment with dexamethasone
Shoji et al., 2023	Cohort, Retro-spective Propensity score-matched cohorts	Japan	Hospitalized patients with COVID-19 Age range: <18 years	Propensity-score-matched patients: • RDV, *n* = 30 • No RDV, *n* = 30	Median LOS: • RDV, 7 days • No RDV, 7 days PICU stay: • RDV, 0 • No RDV, 1	• RDV, 0 • No RDV, 0	Adverse events not reported	• Retrospective • Small cohort • Data collected during the study period did not include reporting of adverse events

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