HAWAIʻI PACIFIC HEALTH | KAPIʻOLANI PALI MOMI STRAUB WILCOX

CREATING A HEALTHIER HAWAIʻI

HPH Summary - FDA EUA of Veklury (remdesivir)

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The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of Veklury (remdesivir, RDV) for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized pediatric patients weighing 3.5kg to less than 40kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5kg.

Indications and Usage	Treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5kg to less than 40kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5kg for whom use of an IV agent is clinically appropriate.
Dosage	<u>5-day regimen for patients NOT requiring mechanical ventilation and/or ECMO:</u> 3.5-<40kg: 5mg/kg IV on Day 1, then 2.5mg/kg IV q24h on Days 2-5. ≥40kg: 200mg IV on Day 1, then 100mg IV q24h on Days 2-5. If patient does not demonstrate clinical improvement, may extend treatment up to a total of 10 days. <u>10-day regimen for patients requiring mechanical ventilation and/or ECMO:</u> 3.5-<40kg: 5mg/kg IV on Day 1, then 2.5mg/kg IV q24h on Days 2-10. ≥40kg: 200mg IV on Day 1, then 100mg IV q24h on Days 2-10. <u>Required labs at baseline and when clinically appropriate while receiving RDV:</u> - eGFR (SCr if 7-28 days old) - Hepatic labs - PT
Special Populations	<u>Renal Impairment:</u> Not recommended in pediatric patients (>28 days old) with eGFR <30ml/min or in full-term neonates (7-28 days old) with SCr ≥ 1.0.
Administration	Administer by IV infusion over 30-120 minutes. Must be reconstituted and further diluted prior to IV infusion.
Contraindications	Use in patients with a history of clinically significant hypersensitivity reactions to RDV or any of its components.
Warnings/ Precautions, Adverse Reactions	There are limited clinical data available for use in this patient population. Serious and unexpected adverse events may occur that have not been previously reported. <u>Hypersensitivity including infusion-related and anaphylactic reactions</u> Hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been observed during and following administration of RDV. S/sx may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (max 120 min) may be considered. If s/sx of a clinically significant

	hypersensitivity reaction occur, immediate discontinue administration of RDV and initiate appropriate treatment. <u>Increased risk of transaminase elevations</u> Transaminase elevations have been reported in patients with COVID-19 who have received RDV. Perform hepatic lab testing in all patients before starting RDV and during treatment as clinically appropriate. - Consider discontinuing RDV if ALT levels increase to greater than 10x ULN. - Discontinue RDV if ALT elevation is accompanied by s/sx of liver inflammation. <u>Risk of Reduced Antiviral Activity when Coadministered with Chloroquine Phosphate or Hydroxychloroquine Sulfate</u> Coadministration with chloroquine or hydroxychloroquine is not recommended due to an antagonistic effect of chloroquine on the metabolic activation and antiviral activity of RDV.
Storage	Store unopened vials below 30C until required for use. After reconstitution, use immediately to prepare diluted solution. Diluted infusion bags: Store for no more than 24h at room temp (20-25C) or 48h at refrigerated temp (2-8C) prior to administration. Diluted infusion syringes: Use immediately.
Dosage Forms	The only authorized dosage form of RDV covered by this EUA is Veklury for injection supplied as a 100mg lyophilized powder in vial.

Mandatory EUA Requirements for RDV Administration:

1. RDV is authorized for treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg *or* hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg for whom use of an IV agent is clinically appropriate and who are under the care or consultation of a licensed clinician skilled in the diagnosis and management of patients with potentially life-threatening illness and medication-related adverse events.

2. As the healthcare provider, communicate to the parent/caregiver and your patient, as age appropriate, information consistent with the "Fact Sheet for Parents and Caregivers" prior to the patient receiving RDV. Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the parent/caregiver has been:
   - o Given the "Fact Sheet for Parents and Caregivers,"
   - o Informed of alternatives to receiving RDV, and
   - o Informed that RDV is an approved drug that is authorized for this unapproved use under EUA.

3. Pediatric patients (greater than 28 days old) must have an eGFR determined and full-term neonates (at least 7 days to less than or equal to 28 days old) must have serum creatinine determined before starting RDV and monitored during treatment as clinically appropriate.

4. Perform hepatic laboratory testing in all patients before starting RDV and during treatment as clinically appropriate.

5. Determine prothrombin time in all patients before starting RDV and monitor during treatment as clinically appropriate.

6. Patients with known hypersensitivity to any ingredient of RDV must not receive RDV.

7. The prescribing healthcare provider and/or the provider's designee are/is responsible for mandatory responses to requests from FDA for information about adverse events and medication errors following administration of RDV.

8. The prescribing healthcare provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events* considered to be potentially related to RDV occurring during RDV treatment within 7 calendar days from the onset of the event.
*Serious Adverse Events are defined as:
- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

The full FDA EUA Fact Sheet for Healthcare Providers may be accessed at:
https://www.fda.gov/media/137566/download.

Reference:

1. FDA Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Veklury (remdesivir) for Hospitalized Children Weighing 8 pounds (3.5kg) to Less Than 88 pounds (40 kg) or Hospitalized Children Less Than 12 Years of Age Weighing at Least 8 pounds (3.5kg) with Coronavirus Disease 2019 (COVID-19). Available at: https://www.fda.gov/media/137566/download. Accessed October 26, 2020.