Indian Health Service
National Pharmacy and Therapeutics Committee
Pharmacovigilance Drug Safety Alert

November 10, 2020

Remdesivir (Veklury®) Prescribing Information Update

The purpose of this Drug Safety Alert is to highlight changes made in the Prescribing Information (PI).

Background: On October 22, 2020, the FDA approved remdesivir for adult and pediatric patients 12 years of age and older and weighing at least 88 pounds (40kg) for the treatment of COVID-19 requiring hospitalization. Previously, remdesivir was available under an Emergency Use Authorization (EUA) described in the NPTC Emerging Treatments Update.

Indication: For adult and pediatric patients 12 years of age and older and weighing at least 88 pounds (40kg) for the treatment of COVID-19 requiring hospitalization.

Recommended Dosing: Adults and pediatric patients 12 years or older and weighing > 40kg:
-200 mg IV on day 1, then 100 mg IV daily for 5 or 10 days.

Duration of therapy is determined by the need for mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO). In patients receiving mechanical ventilation and/or ECMO, 10 days of remdesivir are recommended. Patients not mechanically ventilated &/or provided ECMO should receive 5 days of remdesivir. Dosing for patients <12 years of age or <40kg was removed from the PI.

Warnings/Cautions:

- Not recommended if eGFR ≤ 30ml/min (or receiving dialysis), or if ALT is >10 times ULN (the EUA cutoff was >5 times ULN).
- Remdesivir should be discontinued immediately if clinically significant infusion-related reactions occur (i.e., hypotension, nausea, vomiting, diaphoresis).
- Co-administration of remdesivir and hydroxychloroquine not recommended.

Patient Monitoring:

- Renal and hepatic monitoring prior to initiating, then as clinically warranted (the EUA required daily monitoring).
- Discontinue if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- Prothrombin Time (PT) required prior to initiating, then as clinically warranted

Storage: Once diluted, remdesivir can be stored at room temperature for 24 hours or refrigerated for 48 hours (the EUA limited storage to 4 hours at room temperature and 24 hour refrigerated).

Adverse Reactions: The most common reactions are nausea and increases in ALT/AST.

Report all significant or unusual Adverse Drug Events (ADE) to the FDA MedWatch program as described in the Indian Health Manual. Instructions for submitting an ADE can be found on the IHS Pharmacovigilance website. Please ensure “IHS” or “Indian Health Service” is entered in the Reporter Information section of the form (section G).