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FDA Emergency Use Authorization for Remdesivir

As of May 1, 2020, the FDA has issued an Emergency Use Authorization for the use of remdesivir for the treatment of suspected or laboratory confirmed COVID-19 in adults and children hospitalized with severe disease. Severe disease is defined as patients with an SaO2 $\leq$ 94% on room air or patients requiring supplemental O2, mechanical ventilation, or ECMO.

The optimal duration of treatment for COVID-19 is unknown; both 5- and 10-day regimens have been described. The suggested dose of remdesivir for adults and children $\geq$ 40 kg is a single loading dose of 200 mg infused IV over 30-120 minutes on Day 1 followed by once-daily maintenance doses of 100 mg IV over 30-120 minutes Days 2-5 or Days 2-10.

The suggested dose of remdesivir for children between 3.5 kg and 40 kg is a single loading does of 5 mg/kg IV infused over 30-120 minutes on Day 1 followed by once daily maintenance doses of 2.5 mg/kg IV infused over 30-120 minutes on Days 2-5 or Days 2-10.

All patients must have an eGFR determined before dosing, and hepatic laboratory testing should be performed prior to starting remdesivir and daily while receiving remdesivir.

Providers are cautioned regarding the use of remdesivir in pregnancy or in patients with hepatic or renal impairment.

Side effects and complications of remdesivir include infusion-related reactions and transaminase elevation.

For more detailed guidance regarding the use of remdesivir for the treatment of COVID-19, please refer to FDA guidance: https://www.fda.gov/media/137566/download.