May 4, 2020

COM-2020-036

Dear provider of healthcare-related services,

On May 1, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the drug 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 low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator.

Remdesivir is an investigational antiviral drug to be administered intravenously, whose safety and efficacy for the treatment of COVID-19 are being evaluated in multiple ongoing clinical trials. Preliminary data from a placebo-controlled clinical trial suggested that treatment with remdesivir resulted in faster time to recovery as compared to placebo. The FDA is authorizing the emergency use of remdesivir to treat hospitalized patients with severe COVID-19 because it may help very sick patients.

Please refer to the full letter of authorization for additional important details such as the scope of authorization, the specific conditions that must be met, etc.

Additional information can be found at the FDA's Emergency Use Authorization portal and on the "Frequently Asked Questions on the EUA for Remdesivir for Certain Hospitalized COVID-19 Patients".

The situation with the COVID-19 pandemic is dynamic and continuously changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most actualized information.

PharmPix is committed to the health and wellness of our members. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137.

Regards,

Clinical Department

References:

1. Emergency Use Authorization - Therapeutics. (2020). Retrieved May 2020, from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics

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