October 26, 2020

COM-2020-084

Dear provider of pharmaceutical services,

On October 22, 2020, the U.S. Food and Drug Administration (FDA) announced the antiviral drug Remdesivir (brand name Veklury®) as the first and only FDA-Approved treatment for COVID-19 at the moment. Veklury® was approved for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization.

On May 1, 2020, the FDA issued an Emergency Use Authorization (EUA) for the emergency use of Veklury®. The difference between this approval and the EUA is the population to be treated with the drug. To ensure continued access to the pediatric population previously covered, the FDA revised the EUA for Veklury® to authorize the drug's use for the 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.

Veklury® was approved based on the assessment of the three clinical trials, including a randomized, double-blind, placebo-controlled clinical trial (ACTT-1). The results revealed that in hospitalized subjects with mild, moderate, and severe COVID-19, the recovery time was reduced to 10 days after using the drug compared to 15 days with placebo plus standard of care. Moreover, two follow up studies evaluated a 5 days and 10 days regimen of treatment and found that the odds of improving a subject's COVID-19 symptoms were similar in both groups and the odds of improving were higher in the 5-day group compared to standard treatment. Clinical trials assessing the safety and efficacy of Veklury® in the pediatric patient population are ongoing. Additional information can be found at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We encourage the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated 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 disease 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. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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Regards,

Clinical Department

References:

U.S. Food and Drug Administration. (2020). FDA Approves First Treatment for COVID-19 : Remdesivir. U.S. Food & Drug Administration. Retrieved from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.

FDA's approval of Veklury (remdesivir) for the treatment of COVID-19. (2020). Retrieved from https://www.fda.gov/drugs/drug-safety-and-availability/fdas-approval-veklury-remdesivir-treatment-covid-19-science-safety-and-effectiveness

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