December 11, 2020

COM-2020-095

Dear provider of healthcare-related services,

On November 19, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of baricitinib (Olumiant), in combination with remdesivir (Veklury), for the treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19), in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Of note, although **baricitinib (Olumiant)** is currently FDA-approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies, it is **NOT FDA-APPROVED FOR THE TREATMENT OF COVID-19**. In addition, under the EUA, baricitinib (Olumiant) can not be used in combination with remdesivir (Veklury) outside the hospital setting.

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 Emergency Use Authorization for Olumiant (baricitinib) in Combination with Veklury (remdesivir) for Treatment of Mild to Moderate COVID-19".

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 our members' health and wellness. 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. In addition, you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

Clinical Department

References:

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

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