December 11, 2020

COM-2020-096

Dear provider of healthcare-related services,

On November 21, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of casirivimab and imdevimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Casirivimab and imdevimab are recombinant human IgG1 monoclonal antibodies that target the receptor binding domain of the spike protein of SARS-CoV-2. They are investigational drug products and are **NOT FDA-APPROVED FOR ANY INDICATION**.

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 of Casirivimab + Imdevimab".

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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