June 2021

COM-2021-031

Dear provider of healthcare-related services,

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for sotrovimab, an unapproved product, 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 progression to severe COVID-19, including hospitalization or death. Important limitations of the authorized use include:

- Sotrovimab is not authorized for use in patients:
    - who are hospitalized due to COVID-19, OR
    - who require oxygen therapy due to COVID-19, OR
    - who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity).

Sotrovimab is an investigational monoclonal antibody that not currently FDA-approved to treat any diseases or conditions, including COVID-19.

Additional information can be found at:

- The FDA's Emergency Use Authorization portal: Emergency Use Authorization 100
- The Fact Sheet For Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab
- The Frequently Asked Questions on the Emergency Use Authorization of Sotrovimab

Since the COVID-19 pandemic is dynamic, 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 updated information. It is also important to keep up-to-date about the role of pharmacists in the COVID-19 vaccination response.

PharmPix is committed to our member's health and wellness and supports you as the COVID-19 pandemic continues to evolve. 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,

PharmPix Clinical Department

References:

- U.S. Food and Drug Administration (FDA). (2021). Emergency Use Authorization. Retrieved from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
- U.S. Food and Drug Administration (FDA). (2021). Fact Sheet For Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab. Retrieved from https://www.fda.gov/media/149534/download
- U.S. Food and Drug Administration (FDA). (2021). Frequently Asked Questions on the Emergency Use Authorization of Sotrovimab. Retrieved from https://www.fda.gov/media/149535/download