April 29, 2021

COM-2021-024

Dear provider of pharmaceutical services,

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) lifted the recommended pause on Johnson & Johnson (Janssen) COVID-19 vaccine use and determined that the use of the vaccine should be resumed.

The use of Janssen COVID-19 vaccine was paused due to recent data that suggested an increased risk of rare blood clots called thrombosis with thrombocytopenia syndrome (TTS). However, after a thorough safety review, the FDA and CDC determined that the known and potential benefits of Janssen COVID-19 vaccine outweigh its known and potential risks in individuals 18 years of age and older. At this time, the available data suggest that the chance of this serious adverse event occurring is very low.

Please refer to the following sources for additional important details:

1. Janssen COVID-19 Vaccine Frequently Asked Questions – The FDA added and updated some questions about resuming the use of this vaccine.

2. Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine – Contains instructions for healthcare providers, dosage and administration details, contraindications, warnings, reported adverse reactions, information to provide to vaccine recipients/caregiver, mandatory requirements for the vaccine administration under EUA, how to report adverse events, information regarding the authority for issuance of the EUA, and the full EUA prescribing information. Has been updated to include a Warning pertaining to the risk of thrombosis with thrombocytopenia.

Additional information can be found at the FDA's COVID-19 Vaccines portal and the Centers for Disease and Control Prevention (CDC) website.

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 and the CDC 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 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. Also, you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

Clinical Department

References:

1. FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review. (2021). Retrieved April 2021, from https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough.
2. Janssen COVID-19 Vaccine Frequently Asked Questions. (2021). Retrieved April 2021, from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/janssen-covid-19-vaccine-frequently-asked-questions.
3. Fact Sheet for Healthcare Providers Administering Vaccine - EUA of the Janssen covid-19 vaccine to prevent COVID-19. (2021). Retrieved April 2021, from https://www.fda.gov/media/146304/download.