

July 15th, 2022

COM-2022-041

Dear provider of healthcare-related services,

We all have important roles in the front lines of the 2019 coronavirus disease (COVID-19) pandemic that we are facing. As the COVID-19 pandemic continues to evolve, PharmPix is making every possible effort to continue to provide our essential services to assure the use of appropriate medications by the appropriate patients at the right moment, while also caring for the safety of our employees, their families, and the community in general.

The FDA has issued an emergency use authorization (EUA) to permit the emergency use of Novavax COVID-19 vaccine, adjuvanted, for active immunization to prevent COVID-19 in individuals 18 years of age and older. The Novavax COVID-19 vaccine is administered as a two-dose primary series (0.5mL each), three weeks apart.

The vaccine was assessed in an ongoing randomized, blinded, placebo-controlled study conducted in the United States and Mexico. The effectiveness of the vaccine was assessed in clinical trial participants 18 years of age and older who did not have evidence of SARS-CoV-2 infection through 6 days after receiving the second dose. Overall, the vaccine was 90.4% effective in preventing mild, moderate or severe COVID-19, with 17 cases of COVID-19 occurring in the vaccine group and 79 cases in the placebo group.

The safety of the vaccine was assessed in approximately 26,000 clinical trial participants who received the vaccine and approximately 25,000 who received placebo. The most common reported side effects by vaccine recipients were pain, tenderness, redness and swelling at the injection site, fatigue, muscle pain, headache, joint pain, nausea, vomiting and fever. The increased risks of myocarditis and pericarditis following the administration of Novavax COVID-19 vaccine was observed in the clinical trials.

The FDA expects Novavax Inc. to continue their clinical trials to obtain additional safety and effectiveness data and pursue approval. The Centers for Disease and Control Prevention (CDC) Advisory Committee on Immunization Practices' (ACIP) is scheduled to meet on July 19 to issue their own recommendation.

Please refer to the following resources for more information regarding Novavax EUA:

- [Fact Sheet for Healthcare Providers: EUA of Novavax COVID-19 Vaccine](#)
- [FDA News Release: FDA Authorized Emergency Use of Novavax COVID-19 Vaccine](#)

The situation with the COVID-19 pandemic is dynamic and constantly 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 updated information.



PharmPix is committed to the health and wellness of our members, and to support 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 220.

Kind regards,

Clinical Department



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