

May 19th, 2022

COM-2022-027

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 U.S. Food and Drug Administration (FDA) has amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine. The EUA authorizes the use of a single booster dose for administration to children 5 through 11 years at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 vaccine.

This amendment is based on FDA's analysis of immune response data in a subset of children from the ongoing randomized placebo-controlled trial. Antibody responses were evaluated in 67 study participants who received a booster dose 7 to 9 months after completing a two-dose primary series of the Pfizer-BioNTech COVID-19 vaccine. The antibody level against the SARS-CoV-2 virus one month after the booster dose was increased compared to before the booster dose. The most commonly reported side effects were pain, redness, swelling at the injection site, fatigue, headache, muscle and joint pain, chills, and fever. The safety information was obtained after assessing the response in approximately 400 children who received a booster dose at least five months (range 5 to 9 months) after completing a two-dose primary series.

Please refer to the following resources for more information:

1. [COVID-19 Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years](#)
2. [Fact Sheet for Healthcare Providers Administering Vaccine \(for 5 through 11 years of age\)](#)
3. [Summary of EUA for Pfizer-BioNTech COVID-19 Vaccine](#)



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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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