



May 13, 2021

****Emergency Use Authorization (Expanded Use)****

Pfizer-BioNTech COVID-19 Vaccine in adolescents aged 12-15 years

Vaccine Platform & Mechanism of Action¹: Messenger RNA (mRNA)-based vaccine; mRNA vaccines introduce mRNA that encodes a disease-specific antigen, in this case the SARS-CoV-2 spike protein (which helps the virus attach to and invade cells), and leverage the host cells' protein synthesis machinery to produce antigens that elicit the immune response. The production of these foreign antigens prepares the immune system to recognize this viral antigen so it is ready to combat future infections caused by virus with the same antigen.

Current Status^{2,3}: On December 11, 2020, the U.S Food and Drug Administration (FDA) issued an [Emergency Use Authorization \(EUA\)](#) for the Pfizer-BioNTech COVID-19 Vaccine for prevention for COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. It is not currently FDA-approved for any indication. **On May 10, 2021, the FDA reissued and expanded the Pfizer-BioNTech COVID-19 Vaccine EUA to include individuals aged 12 to 15 years.** This action introduces the first authorized COVID-19 vaccine available in this pediatric population. Of interest, Pfizer and BioNTech are also conducting a pediatric study evaluating the safety and efficacy of the vaccine in children aged 6 months to 11 years of age.

Efficacy²: FDA reviewed effectiveness data from the ongoing global Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% CI: 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose, with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group.

Based on these data, the FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

Safety^{2,4,5}: FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%). Of particular interest, syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Report all significant or unusual Adverse Vaccine Events (AVE) to the VAERS program as described in the [Indian Health Manual](#). Instructions for submitting an AVE can be found on the [IHS Pharmacovigilance website](#).

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CDC Advisory Committee on Immunization Practices (ACIP)^{6,7}: On May 12, 2021, the ACIP met and voted unanimously (14-0) to recommend use of the Pfizer-BioNTech mRNA vaccine in individuals aged 12 to 15 years in the United States, stating it was safe and effective. The review included important clinical considerations. Regarding co-administration of vaccines, the CDC Adolescent Talking Points (also issued May 12, 2021) state the COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov . For more information about the NPTC, please visit the [NPTC website](#).

References:

1. Li, Yingzhu. American Chemical Society blog. [Meet the mRNA vaccine rookies aiming to take down COVID-19](#). Accessed 11-30-20.
2. U.S. Food and Drug Administration. [Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization reissued 05-10-2021](#).
3. Pfizer News Release; March 31, 2021. [Pfizer-BioNTech Announce Positive Topline Results of Pivotal COVID-19 Vaccine Study in Adolescents](#). Accessed May 12, 2021.
4. Pfizer News Release; May 10, 2021 [Pfizer and BioNTech Receive First US Authorization for Emergency Use of COVID-19 Vaccine in Adolescents](#). Accessed May 12, 2021.
5. U.S. Food and Drug Administration. [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE](#). Revised: 10 May 2021.
6. U.S. Centers for Disease Control and Prevention. [Media Statement: CDC Director Statement on Pfizer's Use of COVID-19 Vaccine in Adolescents Age 12 and older](#). Issued May 12, 2021.
7. U.S. Centers for Disease Control and Prevention. [ACIP Presentation Slides: May 12, 2021 Meeting](#). Accessed May 13, 2021.