



January 6, 2022

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

**FDA Takes Multiple Actions to Expand Use of Pfizer-BioNTech COVID-19 Vaccine**

**Background & Current Status<sup>1,2</sup>:**

- 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.
- On May 10, 2021, the FDA expanded the Pfizer-BioNTech COVID-19 Vaccine EUA to include individuals aged 12 to 15 years.
- On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 Vaccine, now known as Comirnaty®, for the prevention of COVID-19 in individuals aged 16 years and older.
- On October 29, 2021, the FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age.
- On November 19, the FDA authorized the use of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine to all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine.
- On December 9, 2021, the FDA amended the Pfizer-BioNTech COVID-19 Vaccine EUA, authorizing use of a single booster dose for administration to individuals 16 and 17 years of age at least six months after completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine.

**On January 3, 2022, the amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to:**

- *Expand the use of a single booster dose to include use in individuals 12 through 15 years of age.*
- *Shorten the time between the completion of primary vaccination of the Pfizer-BioNTech COVID-19 Vaccine and a booster dose to at least five months.*
- *Allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.*

**Vaccine Data for Patient Subgroups<sup>1</sup>:**

**(1) Boosters are now authorized for people 12 years of age and older**

This action expands the use of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine to include its use in individuals as young as 12 years of age.

- The agency has determined that the protective health benefits of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death, outweigh potential risks in individuals aged 12 through 15 years.
- The FDA reviewed real-world data from Israel, including safety data from more than 6,300 individuals 12 through 15 years of age who received a booster dose of the vaccine at least 5 months following completion of the primary two-dose vaccination series. These additional data enabled the FDA to reassess the benefits and risks of the use of a booster in the younger adolescent population in the setting of the current surge in COVID-19 cases.
- The data shows there are no new safety concerns following a booster in this population. There were no new cases of myocarditis or pericarditis reported to date in these individuals.

**(2) Booster interval updated to five months for people 12 years of age and older**

The FDA is also authorizing the use of a single booster dose five months after completion of the primary vaccination series of the Pfizer-BioNTech COVID-19 Vaccine.

- Since Pfizer initially submitted safety and effectiveness data on a single booster dose following primary vaccination, additional real-world data have become available on the increasing number of cases of COVID-19 with the omicron variant in the U.S.
- No new safety concerns have emerged from a population of over 4.1 million individuals 16 years of age and older in Israel who received a booster dose at least five months following completion of the primary vaccination series.
- Additionally, peer-reviewed data indicate that a booster dose of the Pfizer-BioNTech COVID-19 Vaccine greatly improves an individual's antibody response to be able to counter the omicron variant. Authorizing booster vaccination to take place at five months rather than six months may therefore provide better protection sooner for individuals against the highly transmissible omicron variant. Given the demonstrated safety and effectiveness of a

booster dose when administered five months after the primary vaccination series, and the fact that a booster dose may help provide better protection against the rapidly spreading omicron variant, the FDA has determined that the known and potential benefits of administering a booster to individuals ages 12 and older at least five months following completion of the primary vaccination series, outweighs the known and potential risks.

### **(3) A third primary series dose for certain immunocompromised children ages 5 through 11**

Children 5 through 11 years of age who have undergone solid organ transplantation, or who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise, may not respond adequately to the two-dose primary vaccination series. Thus, a third primary series dose has now been authorized for this group. This will now allow these children to receive the maximum potential benefit from vaccination.

- The FDA previously authorized a third primary series dose for use as part of the primary immunization series in individuals 12 years and older. The potential effectiveness of an additional dose in children 5 through 11 years of age was extrapolated from data in adults.
- The agency used prior analyses conducted as part of the authorization process for healthy children to inform safety in this population and determined that the potential benefits of the administration of a third primary series dose at least 28 days following the second dose of the two-dose regimen, outweighed the potential and known risks of the vaccine. To date, the FDA and CDC have seen no new safety signals in this age group.
- **Children 5 through 11 years of age who are fully vaccinated and are not immunocompromised do not need a third dose at this time, but the FDA will continue to review information and communicate with the public if data emerges suggesting booster doses are needed for this pediatric population.**

### **ACIP Recommendations<sup>3</sup>:** Summary of recent actions (last updated January 5, 2022):

The CDC's Advisory Committee on Immunization Practices (ACIP) met January 5, 2022 and voted to recommend a **single booster dose of Pfizer-BioNTech COVID-19 vaccine for persons aged 12-17 years at least 5 months after primary series.** This recommendation, approved by the CDC, will;

- Extend booster dose eligibility to adolescents ages 12-15 yo.
- Reduce the interval for Pfizer-BioNTech booster dose eligibility to 5 months.
- Strengthen the recommendation from "may receive" to "should receive" a booster dose for 12-17 yo adolescents.

These approved recommendations will be reflected in the updated [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines](#).

### **Current EUA Fact Sheets<sup>4-7</sup>:**

As a convenience, Fact Sheets for the Pfizer-BioNTech COVID-19 Vaccine are accessible below:

- ❖ (1) [Healthcare Providers](#) -OR- (2) [Recipients and Caregivers](#) (for 5-11 years only)
- ❖ (1) [Healthcare Providers](#) -OR- (2) [Recipients and Caregivers](#) (for 12 years and older)

### **Mandatory Requirements under the EUA<sup>6,7</sup>:**

- Use Pfizer-BioNTech COVID Vaccine only in authorized patients described in the respective Fact Sheets.
- Communicate to recipients or caregivers, as age appropriate, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to receiving Pfizer-BioNTech COVID-19 Vaccine.
- Include vaccination information in the local jurisdiction's Immunization Information System or other system.
- Mandatory reporting of the following to the [Vaccine Adverse Event Reporting System \(VAERS\)](#):
  - Vaccine administration errors whether or not associated with an adverse event,
  - Serious adverse events (irrespective of attribution to vaccination),
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
  - Cases of COVID-19 that result in hospitalization or death.
- Respond to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer BioNTech COVID-19 Vaccines to recipients.
- **Federal, Tribal, and Urban programs are all encouraged to put "IHS" into field #26 of the form.**

#### **References:**

1. Food and Drug Administration. FDA News Release. [Coronavirus \(COVID-19\) Update: FDA Takes Multiple Actions to Expand Use of Pfizer-BioNTech COVID-19 Vaccine](#). Published online on January 3, 2022.
2. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine [EUA Letter of Authorization](#). Issued January 3, 2022.
3. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices (ACIP). ACIP Presentation Slides. [Meeting, January 5, 2022](#).
4. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine (for 5-11 years only): [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE](#). Revised: January 3, 2022.
5. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine (for 5-11 years only): [FACT SHEET FOR RECIPIENTS & CAREGIVERS](#). Revised: January 3, 2022.
6. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine (for 12 years and older): [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE](#). Revised: January 3, 2022.
7. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine (for 12 years and older):: [FACT SHEET FOR RECIPIENTS & CAREGIVERS](#). Revised: January 3, 2022