



September 24, 2021

## **FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations (UPDATES to the Emergency Use Authorization)**

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 of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. On May 10, 2021, the FDA reissued and 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 (COMIRNATY<sup>®</sup>) in individuals ages 16 years and older.

On September 22, 2021, the FDA amended<sup>1</sup> the EUA for the [Pfizer BioNTech COVID-19 Vaccine](#)<sup>2</sup> noting the following;

- **Authorization for emergency use the administration of a single booster dose of COMIRNATY<sup>®</sup> (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in certain populations.**

The FDA considered the data that the vaccine manufacturer submitted, information presented at the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting, and the committee's discussion, and determined that based on the totality of the available scientific evidence, a booster dose of Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 and that the known and potential benefits of a booster dose outweigh the known and potential risks in the populations that the FDA is authorizing for use. The booster dose is authorized for administration to these individuals at least six months following completion of their primary series and may be given at any point after that time.

It is important to note that;

- The FDA-authorized Pfizer-BioNTech COVID-19 Vaccine is the same formulation as the FDA-approved COMIRNATY<sup>®</sup> and the vaccines may be used interchangeably.

### **Centers for Disease Control and Prevention (CDC) Approval and Indications**<sup>3</sup>

On September 24, 2021, the CDC Director endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings.

The CDC recommends:<sup>3</sup>

- people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

## **Implementation Guidance:**

- ***These recommendations only apply to those individuals who received a primary two-dose series of the Pfizer-BioNTech COVID-19 vaccine.***
- ***COVID-19 vaccines from different manufacturers are non-interchangeable. Only a Pfizer-BioNTech COVID-19 vaccine should be administered as a booster dose to eligible recipients.***
- ***Currently, there is insufficient evidence to support booster doses of the Moderna or Johnson and Johnson/Janssen COVID-19 Vaccine.***

According to the CDC's Interim [Clinical Considerations](#)<sup>4</sup> for Use of COVID-19 Vaccines, based on available evidence from published reports, scientific articles in press, unreviewed preprints, and internal data, certain [underlying medical conditions](#)<sup>5</sup> are associated with a high risk for severe COVID-19.

As a convenience, the accompanying **EUA Fact Sheets** are accessible immediately below.

1. Fact Sheet, Pfizer-BioNTech COVID-19 Vaccine – [For Healthcare Providers](#) (HCP)
2. Fact Sheet, Pfizer-BioNTech COVID-19 Vaccine – [Recipients and Caregivers](#)

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

- Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 12 years of age and older.
- Communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.
- Include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.
- 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 Vaccine to recipients.
- 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.*
  - ***Should include the words "Indian Health Service" or "IHS" on the form in item #26.***

## **References:**

1. [News Release](#): FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations. September 22, 2021.
2. U.S. Food and Drug Administration. [Letter of Authorization](#) (EUA) Reissued: Pfizer-BioNTech COVID-19 Vaccine. September 22, 2021.
3. [News Release](#): CDC Statement on ACIP Booster Recommendations. September 24, 2021.
4. [Interim Clinical Considerations](#) for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Accessed September 24, 2021.
5. Underlying Medical Conditions Associated with High Risk for Severe COVID-19. [Information for Healthcare Providers](#). Accessed September 24, 2021.
6. U.S. Food and Drug Administration. [Fact Sheet for Healthcare Providers](#). Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine. September 22, 2021.
7. U.S. Food and Drug Administration. [Fact Sheet for Recipients and Caregivers](#). Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine, September 22, 2021.