

## Pfizer/BioNTech COVID-19 Vaccine – Expanded emergency use authorization

- On December 9, 2021, the [FDA announced](#) an expanded emergency use authorization (EUA) for the [Pfizer/BioNTech COVID-19 vaccine](#), for a single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 vaccine or Comirnaty®.
  - Previously, a single booster dose was indicated for individuals 18 years and older.
- Additionally, the Pfizer/BioNTech COVID-19 vaccine is authorized under EUA for:
  - A 2-dose primary series to individuals 12 through 15 years of age
  - A 2-dose primary series to individuals 5 through 11 years of age ([orange cap](#))
  - A third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and
  - A single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine.
- Comirnaty is an FDA-approved COVID-19 vaccine that is indicated for active immunization as a 2-dose primary series to prevent COVID-19 in individuals 16 years of age and older.
- The EUA for a single booster dose of the Pfizer-BioNTech COVID-19 vaccine for individuals 16 and 17 years of age is based on the FDA's previous analysis of immune response data that supported use of a booster dose in individuals 18 years of age and older.
- The FDA has determined that the benefits of a single booster dose of the Pfizer-BioNTech COVID-19 vaccine or Comirnaty outweigh the risks of myocarditis and pericarditis in individuals 16 and 17 years of age to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death.
- The recommended dose of the Pfizer/BioNTech COVID-19 vaccine for a booster dose in individuals 16 years of age and older is a single dose (0.3 mL) administered at least 6 months after completing a primary series of the Pfizer/BioNTech COVID-19 vaccine or Comirnaty.
  - This is the same dose as the primary series for the Pfizer/BioNTech COVID-19 vaccine.

### What's Next:

- As a reminder of the process, FDA issues the authorization, ACIP reviews the data and recommends the proper use, the CDC Director must then verify the ACIP recommendations before they become official.
- The CDC has not yet scheduled an [Advisory Committee on Immunization Practices \(ACIP\)](#) meeting.