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

- On January 3, 2022, the FDA announced expanded emergency use authorization (EUA) for the Pfizer/BioNTech COVID-19 vaccine, for the following:

    — 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 in individuals 12 years and older.
    — Allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.

- Additionally, the Pfizer/BioNTech COVID-19 vaccine is authorized under existing EUA for the following uses:

    — A 2-dose primary series to individuals 12 through 15 years of age
    — A 2-dose primary series to individuals 5 thought 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 12 through 15 years of age is based on 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.

    — 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.

- The EUA for a single booster dose five months after completion of the primary vaccination series of the Pfizer/BioNTech COVID-19 vaccine for individuals 12 years and older is based on peer-reviewed data from multiple laboratories indicating 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.

    — In addition, 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.

- The EUA for a third primary series dose for certain immunocompromised children 5 through 11 years of age is based on extrapolated data in adults.

- The recommended dose of the Pfizer/BioNTech COVID-19 vaccine (purple cap or grey cap) for a single booster dose in individuals 12 through 15 years of age is 0.3 mL intramuscularly (IM)

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administered at least 5 months after completing a primary series with the Pfizer/BioNTech COVID-19 vaccine or Comirnaty.

  - This is the same dose as the primary series for the Pfizer/BioNTech COVID-19 vaccine.

- The recommended dose of the Pfizer/BioNTech COVID-19 vaccine (orange cap) for a third series dose in individuals 5 through 11 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise is 0.2 mL IM at least 28 days following the second dose.

What's Next:

- As a reminder of the process, FDA issues the authorization, the Advisory Committee on Immunization Practices (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 scheduled an ACIP meeting for January 5 from 1:00 – 5:00 PM EST.