

CLINICAL ALERT

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PharMerica

FDA/CDC Issue COVID-19 Booster Updates

MODERNA, PFIZER COVID-19 Bivalent Booster Vaccines Receive EUA for Use in Younger Age Groups NOVAVAX (Adjuvanted, Monovalent) COVID-19 Vaccine Receives EUA for First Booster Dose

Updates

10/12/22: U.S. Food and Drug Administration (FDA) issues [press release](#) on recently amended **Emergency Use Authorizations (EUA)** to the **MODERNA Bivalent COVID-19 Booster Vaccine** and **PFIZER Bivalent COVID-19 Booster Vaccine** to authorize their use as single booster doses in younger age groups.

MODERNA: bivalent booster authorized in children down to **6 years of age**. The authorizations are for a 25µg booster dose for children ages 6 – 11 years and a 50µg booster dose for ages 12 years and older, each ≥ 2 months after completing primary series of any authorized COVID-19 vaccine OR a booster.

PFIZER: bivalent booster authorized in children down to **5 years of age**. The authorizations are for a 10µg booster dose for children ages 5 – 11 years and a 30µg booster dose for ages 12 years and older, each ≥ 2 months after completing primary series of any authorized COVID-19 vaccine OR a booster.

10/12/22: Centers for Disease Control and Prevention (CDC) provides corresponding updates to [Interim Clinical Considerations for Use of COVID-19 Vaccines in the U.S.](#) Summary of recent changes (updated October 12, 2022):

- New COVID-19 booster recommendations for people ages 5 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series or previously received monovalent booster dose(s); these recommendations replace all prior booster recommendations for this age group
- Recommendations for use of a bivalent MODERNA booster dose in people ages 6yr+
- Recommendations for use of a bivalent PFIZER booster dose in people ages 5yr+

10/19/22: FDA expands [EUA](#) for NOVAVAX COVID-19 Vaccine for use as a **first booster dose ≥ 6 months** after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals **≥ 18 years of age** for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is **not accessible** or **clinically appropriate**, and to individuals ≥18 years of age who **elect to receive** the NOVAVAX vaccine because they would otherwise not receive a booster.

10/19/22: CDC provides corresponding updates to the [Interim Clinical Considerations for Use of COVID-19 Vaccines in the U.S.](#) Summary of recent changes (updated October 19, 2022):

- Guidance for use of a monovalent NOVAVAX COVID-19 booster dose in people ages 18 years and older in limited situations.

10/21/22: CDC adopts these changes into the reissued [COVID-19 Vaccine Immunization Schedule Guide](#)

10/26/22: CDC adopts these changes into the reissued [Summary Document for Interim Clinical Considerations](#)

These 2 guiding documents (also attached) provide quick-reference resources for healthcare providers involved in providing COVID-19 immunizations. Users are encouraged to navigate to the following webpage for future access, to ensure retrieval of the most current versions:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>