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COVID-19 Update: Bivalent Vaccine Booster Doses Authorized for Children ≥ 5 Years Old

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COVID-19 Update

Bivalent Vaccine Booster Doses Authorized for Children ≥ 5 Years Old

The FDA has expanded its Emergency Use Authorizations (EUAs) for the COVID-19 vaccines manufactured by Pfizer/BioNTech (*Comirnaty*) and Moderna (*Spikevax*) to permit use of the bivalent formulations of these products (containing mRNA from the original and BA.4/5 Omicron strains of SARS-CoV-2) as a booster dose in children as young as 5 years old (Pfizer) or 6 years old (Moderna).¹ The bivalent Pfizer vaccine had previously been authorized for use in persons ≥ 12 years old and the bivalent Moderna vaccine in persons ≥ 18 years old.² Bivalent vaccines are not authorized for primary immunization against COVID-19. The monovalent Pfizer and Moderna COVID-19 vaccines are no longer authorized for use as booster doses in any age group.¹

No data on use of the bivalent vaccines in the populations for which it was newly authorized are available. Expansion of the EUAs was based on the results of efficacy trials of the corresponding monovalent vaccines in these age groups and of immunogenicity and safety trials of bivalent vaccines containing mRNA from the original and BA.1 Omicron strains of SARS-CoV-2 (not authorized in the US) in adults.^{1,2}

CDC guidelines recommend that persons ≥ 5 years old who have completed a primary immunization series with any COVID-19 vaccine receive a booster dose of either the bivalent Pfizer vaccine or (in persons ≥ 6 years old) the bivalent Moderna vaccine ≥ 2 months after their most recent monovalent vaccine dose.³ The booster doses of the bivalent Pfizer vaccine are 10 mcg/0.2 mL (orange-capped vials) in children 5-11 years old and 30 mcg/0.3 mL (gray-capped vials) in persons ≥ 12 years old.⁴ The booster doses of the bivalent Moderna vaccine are 25 mcg/0.25 mL in children 6-11 years old and 50 mcg/0.5 mL in persons ≥ 12 years old.⁵ ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes Moderna and Pfizer-BioNTech bivalent COVID-19 vaccines for use as a booster dose in younger age groups. October 12, 2022. Available at: <https://bit.ly/3T0Z2CN>. Accessed October 14, 2022.
2. COVID-19 Update: Bivalent Pfizer and Moderna COVID-19 vaccines for booster immunization. *Med Lett Drugs Ther* 2022; 64:159.
3. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. October 12, 2022. Available at: <https://bit.ly/3KgPdxl>. Accessed October 14, 2022.
4. FDA. Pfizer-BioNTech COVID-19 vaccines. October 12, 2022. Available at: <https://bit.ly/3Mz59fj>. Accessed October 14, 2022.
5. FDA. Moderna COVID-19 vaccines. October 12, 2022. Available at: <https://bit.ly/3MwVyWk>. Accessed October 14, 2022.

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