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IN THIS ISSUE

COVID-19 Update: FDA Expands Bivalent Vaccine Use, Revises Vaccination Schedules

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COVID-19 Update

FDA Expands Bivalent Vaccine Use, Revises Vaccination Schedules

The FDA has amended its Emergency Use Authorizations (EUAs) for the bivalent mRNA COVID-19 vaccines (original and Omicron BA.4/5 strains) manufactured by Pfizer/BioNTech (*Comirnaty*) and Moderna (*Spikevax*) to permit their use for all doses administered to persons ≥ 6 months old. The monovalent Pfizer and Moderna vaccines are no longer authorized for use in the US.¹

All persons ≥ 6 months old who completed a primary series with the Pfizer or Moderna monovalent vaccine may now receive a single dose of bivalent vaccine; an additional bivalent dose can generally be given to persons ≥ 65 years old and to those with significant

immunocompromise. For unvaccinated persons ≥ 5 years old (Pfizer) or ≥ 6 years old (Moderna), a single bivalent dose is now recommended for primary immunization; multiple doses are recommended for younger children. The new recommendations for the Pfizer and Moderna vaccines are summarized in Table 1.¹⁻³ ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes changes to simplify use of bivalent mRNA COVID-19 vaccines. April 18, 2023. Available at: <https://bit.ly/3A9IguO>. Accessed May 1, 2023.
2. FDA. Pfizer-BioNTech COVID-19 vaccines. Pfizer-BioNTech COVID-19 vaccine, bivalent now authorized for all doses. April 18, 2023. Available at: <https://bit.ly/3Mz59fj>. Accessed May 1, 2023.
3. FDA. Moderna COVID-19 vaccines. Moderna COVID-19 vaccine, bivalent now authorized for all doses. April 18, 2023. Available at: <https://bit.ly/3MwVyWk>. Accessed May 1, 2023.

Table 1. Vaccination Recommendations for Pfizer and Moderna COVID-19 Vaccines

Age	Dose/Vial Cap Color	Not Previously Vaccinated Against COVID-19	Vaccination Schedule ¹	
			Previously Received Monovalent Vaccine Only ²	Previously Received ≥ 1 Bivalent Dose ³
Pfizer/BioNTech Bivalent Vaccine (<i>Comirnaty</i>)				
6 mos-4 yrs	3 mcg/0.2 mL; maroon	3 doses: wk 0, wk 3, and ≥ 8 wks after dose 2	1 previous dose: 1 dose ≥ 3 wks later and 1 dose ≥ 8 wks after dose 2 2 previous doses: 1 dose ≥ 8 wks after last dose 3 previous doses: 1 dose ≥ 2 mos after last dose	None
5-11 yrs	10 mcg/0.2 mL; orange	Single dose	Single dose ≥ 2 mos after last dose	None
≥ 12 yrs	30 mcg/0.3 mL; gray	Single dose	Single dose ≥ 2 mos after last dose	≥ 65 yrs: single booster ≥ 4 mos after first bivalent dose
Moderna Bivalent Vaccine (<i>Spikevax</i>)				
6 mos-5 yrs	25 mcg/0.25 mL; blue 10 mcg/0.2 mL; pink	Two 25-mcg doses 1 mo apart	1 previous dose: one 25-mcg dose ≥ 1 mo later 2 previous doses: one 10-mcg dose ≥ 2 mos after last dose	None
6-11 yrs	25 mcg/0.25 mL; blue	Single dose	Single dose ≥ 2 mos after last dose	None
≥ 12 yrs	50 mcg/0.5 mL; blue	Single dose	Single dose ≥ 2 mos after last dose	≥ 65 yrs: single booster ≥ 4 mos after first bivalent dose

N/A: dose not recommended for this use

1. For immunocompetent persons.

2. Previously received the corresponding monovalent vaccine for ages 6 mos-4 yrs (Pfizer) or 6 mos-5 yrs (Moderna), or with any monovalent vaccine(s) for older ages. Monovalent Pfizer and Moderna vaccines are no longer authorized for use in the US.

3. In addition, for solid-organ transplant recipients and persons with an equivalent level of immunocompromise, a single age-appropriate booster dose may be given ≥ 1 month (Moderna age 6 mos-5 yrs) or ≥ 2 months (Pfizer age ≥ 5 yrs or Moderna age ≥ 6 yrs) after the initial bivalent dose. Additional booster doses may be given at the discretion of the healthcare provider.

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