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COVID-19 Update

New Pfizer and Moderna Vaccine Formulations for 2023-2024

Revised 10/23/23: Table 1 has been updated.

New 2023-2024 formulations of the mRNA COVID-19 vaccines manufactured by Pfizer/BioNTech (*Comirnaty*) and Moderna (*Spikevax*) that more closely target currently circulating variants have been licensed by the FDA for use in persons ≥ 12 years old and made available under FDA Emergency Use Authorizations (EUAs) for use in persons 6 months to 11 years old. The bivalent (original and Omicron BA.4/5) formulations of the Pfizer and Moderna vaccines are no longer authorized for use in the US.¹⁻³

THE NEW VACCINES – The new formulations are monovalent vaccines that code for the spike protein of the XBB.1.5 Omicron strain of SARS-CoV-2.

EFFICACY – No clinical studies evaluating the effectiveness of the new vaccine formulations are available. Licensure and authorization of both vaccines were based on safety and efficacy data with previous formulations of the vaccines and on immunogenicity data showing that the neutralization potency of the new formulations against currently circulating strains of the virus, including XBB.1.5, EG.5 (Eris), FL.1.5.1 (Fornax), and BA.2.86 (Pirola), is similar to that of previous formulations against the SARS-CoV-2 strains that they targeted.^{1,4,5}

Table 1. Vaccination Recommendations for Updated 2023-2024 COVID-19 Vaccines^{1,2}

Age	Dose/Vial Color	Not Previously Vaccinated	Previously Vaccinated
Pfizer/BioNTech Vaccine (<i>Comirnaty</i>) – mRNA vaccine			
6 months-4 years ³	3 mcg/0.3 mL; yellow cap and label	3 3-mcg doses: 1st at week 0, 2nd at week 3, and 3rd ≥ 8 weeks after dose 2	<ul style="list-style-type: none"> ▶ 1 previous Pfizer dose: 1 3-mcg dose ≥ 3 weeks later and 1 dose ≥ 8 weeks after dose 2 ▶ 2 previous Pfizer doses: 1 3-mcg dose ≥ 8 weeks after last dose ▶ 3 previous Pfizer doses: 1 3-mcg dose ≥ 2 months after last dose
5-11 years	10 mcg/0.3 mL; light blue cap and label	1 10-mcg dose	▶ 1 10-mcg dose ≥ 2 months after last dose of any mRNA COVID vaccine
≥ 12 years	30 mcg/0.3 mL; gray cap and label	1 30-mcg dose	▶ 1 30-mcg dose ≥ 2 months after last dose of any COVID vaccine
Moderna Vaccine (<i>Spikevax</i>) – mRNA vaccine			
6 months-4 years ³	25 mcg/0.25 mL; dark blue cap/green label	2 25-mcg doses 1 month apart	<ul style="list-style-type: none"> ▶ 1 previous Moderna dose: 1 25-mcg dose ≥ 1 month after last vaccine ▶ ≥ 2 previous Moderna doses: 1 25-mcg dose ≥ 2 months after last vaccine
5-11 years	25 mcg/0.25 mL; dark blue cap/green label	1 25-mcg dose	▶ 1 25-mcg dose ≥ 2 months after last dose of any mRNA COVID vaccine
≥ 12 years	50 mcg/0.5 mL; blue cap and label	1 50-mcg dose	▶ 1 50-mcg dose ≥ 2 months after last dose of any COVID vaccine
Novavax Vaccine – adjuvanted protein subunit vaccine			
≥ 12 years	5 mcg (plus 50 mcg adjuvant)/0.5 mL; blue cap and label	2 5-mcg doses 3 weeks apart ⁴	▶ 1 5-mcg dose ≥ 2 months after last dose of any COVID vaccine

1. The updated 2023-2024 formula vaccines include a monovalent component that corresponds to the Omicron variant XBB.1.5. Previous bivalent Moderna and Pfizer/BioNTech and monovalent Novavax vaccines are no longer authorized for use in the US. The Johnson & Johnson (Janssen) vaccine is no longer available in the US.
2. For immunocompetent persons. Persons with moderate or severe immunocompromise may receive additional doses of the 2023-2024 COVID-19 formula vaccines based on the clinical judgement of a healthcare provider and personal preference and circumstances; additional doses should be given ≥ 2 months after the last 2023-2024 COVID-19 vaccine dose.
3. Includes children who would turn 5 years old during the vaccination series. All doses should be from the same manufacturer.
4. According to the CDC, an 8-week interval between doses might be optimal for some patients, especially adolescent and young adult males, to reduce the risk of myocarditis and pericarditis (<https://bit.ly/3KgPdxl>).

ADVERSE EFFECTS – Adverse effects of earlier versions of the mRNA COVID-19 vaccines have included injection-site reactions, fatigue, irritability, fever, chills, muscle and joint pain, headache, vomiting, decreased appetite, and lymphadenopathy. Severe allergic reactions and Guillain-Barré syndrome have been reported. Myocarditis and pericarditis can occur; the incidence is highest in adolescent and young adult males.⁶

DOSAGE RECOMMENDATIONS – Generally, **persons ≥5 years old** should receive a single dose of a 2023-2024 vaccine formulation ≥2 months after their previous COVID-19 vaccine dose. **Children 6 months to 4 years old** who have already received ≥2 Pfizer or Moderna vaccine doses should receive a single dose of the corresponding 2023-2024 vaccine ≥8 weeks (Pfizer) or ≥2 months (Moderna) after their most recent dose. Those 6 months to 4 years old who received <2 previous doses should be given additional doses until they have received 3 total doses of the Pfizer vaccine or 2 total doses of the Moderna vaccine. **Children 6 months to 11 years old with immunocompromise** (solid-organ transplant recipients and equivalent) should receive at least 3 total age-appropriate COVID-19 vaccine doses, including at least 1 dose of a 2023-2024 formulation. Dosage recommendations for the updated vaccine formulations are summarized in Table 1.^{2,3}

CDC RECOMMENDATIONS – The CDC recommends that all persons ≥6 months old receive either of the two 2023-2024 mRNA COVID-19 vaccines.⁷ ■

1. FDA News Release. FDA takes action on updated mRNA COVID-19 vaccines to better protect against currently circulating variants. September 11, 2023. Available at: <https://bit.ly/3ZmmVcg>. Accessed September 18, 2023.
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4. K Modjarrad. Monovalent XBB.1.5 BNT162b2 COVID-19 vaccine: ACIP presentation. September 12, 2023. Available at: <https://bit.ly/3sUrBdc>. Accessed September 18, 2023.
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6. CDC. Updated COVID-19 vaccine recommendations are now available. September 12, 2023. Available at: <https://bit.ly/44S6RQs>. Accessed September 18, 2023.
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