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COVID-19 Update

New Pfizer and Moderna Vaccine Formulations for 2024-2025

New 2024-2025 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 persons ≥ 12 years old and made available under FDA Emergency Use Authorizations (EUAs) for use in persons 6 months to 11 years old.¹⁻³ A 2024-2025 formulation of the adjuvanted protein subunit COVID-19 vaccine manufactured by Novavax is expected to become available soon for persons ≥ 12 years old.

THE NEW VACCINES – The new formulations are monovalent vaccines that code for the spike protein of the KP.2 Omicron strain of SARS-CoV-2. KP.2 is a member of the “FLiRT” variant family; as of mid-August 2024, FLiRT variants (e.g., KP.2, KP.2.3, KP.3, KP.3.1.1, LB.1) were causing the majority of COVID-19 cases in the US.^{4,5}

CLINICAL STUDIES – No clinical studies evaluating the immunogenicity or effectiveness of the new vaccine formulations are available. Licensure and authorization of both vaccines were based on the immunogenicity, safety, and efficacy of previous vaccine formulations.¹⁻³

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 2024-2025 vaccine formulation ≥ 2 months after their previous COVID-19 vaccine dose. **Children 6 months to 4 years old** who have already received

Table 1. Vaccination Recommendations for 2024-2025 mRNA COVID-19 Vaccines^{1,2}

Age	Dose/Vial Color	Not Previously Vaccinated	Previously Vaccinated
Pfizer/BioNTech Vaccine (<i>Comirnaty</i>)			
6 months-4 years³	3 mcg/0.3 mL; yellow cap and label	Three 3-mcg doses: 1st at week 0, 2nd at week 3, and 3rd ≥ 8 weeks after dose 2 ⁴	1 previous Pfizer dose: One 3-mcg dose ≥ 3 weeks later and 1 dose ≥ 8 weeks after dose 2 ⁴ ≥ 2 previous Pfizer doses: One 3-mcg dose ≥ 8 weeks after last dose
5-11 years	10 mcg/0.3 mL; blue cap and label	One 10-mcg dose	One 10-mcg dose ≥ 2 months after last dose of any mRNA COVID-19 vaccine
≥ 12 years	30 mcg/0.3 mL; gray cap and label	One 30-mcg dose	One 30-mcg dose ≥ 2 months after last dose of any COVID-19 vaccine
Moderna Vaccine (<i>Spikevax</i>)			
6 months-4 years³	25 mcg/0.25 mL; dark blue cap/green label	Two 25-mcg doses 1 month apart	1 previous Moderna dose: One 25-mcg dose ≥ 1 month after last dose ≥ 2 previous Moderna doses: One 25-mcg dose ≥ 2 months after last dose
5-11 years	25 mcg/0.25 mL; dark blue cap/green label	One 25-mcg dose	One 25-mcg dose ≥ 2 months after last dose of any mRNA COVID-19 vaccine
≥ 12 years	50 mcg/0.5 mL; dark blue cap/blue label	One 50-mcg dose	One 50-mcg dose ≥ 2 months after last dose of any COVID-19 vaccine

1. The 2024-2025 vaccines contain a monovalent component that corresponds to the KP.2 Omicron variant of SARS-CoV-2. A 2024-2025 formulation of the adjuvanted protein subunit COVID-19 vaccine manufactured by Novavax is expected to become available soon.
 2. For immunocompetent persons. Persons with moderate or severe immunocompromise may receive additional doses of the 2024-2025 COVID-19 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 2024-2025 COVID-19 vaccine dose.
 3. All doses should be from the same manufacturer.
 4. In children who turn 5 years old before completion of the vaccination series, instead administer one 10-mcg Pfizer vaccine dose ≥ 2 months after the last 3-mcg dose.

≥2 Pfizer or Moderna vaccine doses should receive a single dose of the corresponding 2024-2025 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 2024-2025 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 2024-2025 mRNA COVID-19 vaccines.⁷ ■

1. FDA News Release. FDA approves and authorizes updated mRNA COVID-19 vaccines to better protect against currently circulating variants. August 22, 2024. Available at: <https://bit.ly/3T3eGzP>. Accessed August 28, 2024.
2. FDA. Fact sheet for healthcare providers administering vaccine: Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 vaccine (2024-2025 formula), for 6 months through 11 years of age. August 22, 2024. Available at: <https://bit.ly/4g2dQxa>. Accessed August 28, 2024.
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7. CDC. Use of COVID-19 vaccines in the United States: interim clinical considerations. August 23, 2024. Available at: <https://bit.ly/3yKjLWV>. Accessed August 28, 2024.

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