COVID-19 Vaccine for the 2023–24 Fall/Winter Virus Season

Background
• On September 11, 2023, the Food and Drug Administration (FDA) authorized the updated (2023–2024 Formula) COVID-19 mRNA vaccines by Moderna and Pfizer-BioNTech for use in persons aged 6 months–11 years under Emergency Use Authorization (EUA) and approved the updated Moderna and Pfizer-BioNTech COVID-19 vaccines for persons aged ≥12 years.1
• On October 3, 2023, FDA authorized the updated Novavax COVID-19 vaccine for use in persons aged ≥12 years under EUA.1
• These vaccines are all monovalent, targeting circulating SARS-CoV-2-XBB-sublineage variants to help protect against COVID-19 hospitalization and death.1
• While anyone can develop severe COVID-19, adults aged ≥65 years and people with underlying medical conditions are at highest risk for COVID-19 hospitalization.2
• The pooled vaccine effectiveness (VE) of last year’s bivalent mRNA vaccines was 53% (95% CI = 50%–56%) against medically-attended COVID-19, 48% (95% CI = 30%–61%) against hospitalization, and 61% (95% CI = 41%–74%) against death.1 The certainty assessment for the VE against death was low due to inconsistency.1

Safety
Post-vaccination reactions were generally similar for Moderna and Pfizer-BioNTech COVID-19 vaccines, including pain at the injection site, fatigue, headache, and myalgia.1 Any adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

General Recommendations
• Everyone aged ≥6 months is recommended to receive one dose of the updated 2023–2024 COVID-19 vaccine.
• For persons aged ≥5 years, 1 dose of an updated 2023–24 vaccine is recommended, regardless of vaccination history.
• For children aged 5–11 years, an mRNA vaccine (Moderna or Pfizer) is recommended.
• For persons aged ≥12 years, Moderna, Pfizer, or Novavax may be used.
• Children aged 6 months through 4 years should complete a multi-dose initial series with at least one dose of the 2023–24 mRNA COVID-19 vaccine; all doses of COVID-19 vaccine should be from the same manufacturer (either 2 doses of Moderna or 3 doses of Pfizer).3
• If a child has completed the primary series with the original monovalent or bivalent vaccines, an additional dose of 2023–24 updated mRNA COVID-19 vaccine should be given of the same manufacturer.3
• For patients who have received prior COVID-19 vaccine doses, the updated vaccine should be administered ≥2 months following the most recent dose.1

Contraindications and Precautions to COVID-19 Vaccination

<table>
<thead>
<tr>
<th>Medical condition or history</th>
<th>Guidance</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of a severe allergic reaction (e.g., urticaria)2 after a previous dose or to a component of the COVID-19 vaccine1</td>
<td>Contraindication</td>
<td>Do not vaccinate with the same COVID-19 vaccine type.3 May administer the alternate COVID-19 vaccine type.3</td>
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<tr>
<td>History of a diagnosed non-severe allergy to a component of the COVID-19 vaccine1</td>
<td>Precaution</td>
<td>May administer the alternate COVID-19 vaccine type.3</td>
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<tr>
<td>Moderate or severe acute illness, with or without fever</td>
<td>Precaution</td>
<td>Defer vaccination until the illness has improved.</td>
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<td>History of multisystem inflammatory syndrome (MIS-C or MIS-A)</td>
<td>Precaution</td>
<td>Review clinical considerations.2</td>
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<tr>
<td>Myocarditis or pericarditis ≤3 weeks after a COVID-19 dose</td>
<td>Precaution</td>
<td>Generally avoid a subsequent dose of any COVID-19.</td>
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Notes:
1 See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).
2 Vaccine type refers to mRNA (Moderna and Pfizer-BioNTech) or protein subunit vaccines (Novavax).
3 Vaccine indications are for use with the updated 2023–2024 COVID-19 vaccines.

References
2. MMWR. COVID-19-Associated Hospitalizations Among U.S. Adults Aged ≥65 Years—COVID-19-NET, 13 States, January–August 2023. 72(40):1089-1094 Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7240a3.htm

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