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TECHNICAL BULLETIN

DATE: January 10, 2025
TOPIC: FDA Approves and Authorizes for Emergency Use Updated COVID-19 Vaccines and De-authorizes Administration of 2023-2024 COVID-19 Vaccines - Update to Recommendation
CONTACT: Jessica Lamb, RN, Nevada State Immunization Program
TO: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

BACKGROUND

On August 22, 2024, the U.S. Food and Drug Administration (FDA) issued approval and granted emergency use authorization (EUA) to both Moderna and Pfizer-BioNTech for their updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2. This is to provide the public with an updated mRNA COVID-19 vaccine formulary that more closely targets currently circulating variants and provides better protection against serious illness and complications from COVID-19.

In addition, from correspondence received from the Centers for Disease Control and Prevention (CDC) on August 23, 2024, all 2023-2024 mRNA COVID-19 vaccines are no longer authorized for use in the United States, regardless of age. Administration of any 2023-2024 mRNA COVID-19 vaccines is now considered a vaccine administration error and must be reported to the Vaccine Adverse Event Reporting System (VAERS). To minimize the risk of vaccine administration errors, providers should:

- Remove all 2023–2024 mRNA COVID-19 vaccines from storage units immediately, even if they are not expired.
- Once all inventory is fully accounted for, delete 2023–2024 mRNA COVID-19 vaccine listings from the available vaccine inventory in your Immunization Information System, as applicable.
- Return all unused 2023–2024 mRNA COVID-19 vaccines to CDC's centralized distributor using the normal process for returning spoiled/expired vaccines.

On August 30, 2024, the FDA amended Novavax's COVID-19 Vaccine EUA to include their 2024-2025 vaccine formula. The Novavax COVID-19, Adjuvanted (2024-2025 formula) includes a monovalent (single) component that corresponds to the Omicron variant JN.1 strain of SARS-CoV-2 for use in individuals 12 years of age and older. In addition to this authorization, FDA also de-authorized the 2023-2024 Novavax COVID-19 Vaccine, Adjuvanted for use in the United States. The 2024-2025 Novavax COVID-19 Vaccine, Adjuvanted is available to the following individuals:

- Individuals 12 years of age and older who have never been vaccinated with any COVID-19 vaccine are eligible to receive 2 doses of this updated vaccine, 3 weeks apart.

- Individuals who have been vaccinated only with 1 dose of any Novavax COVID-19 vaccine are eligible to receive one dose of the updated Novavax COVID-19 vaccine at least 3 weeks after the previous dose.
- Those who have been vaccinated with a prior formula of a COVID-19 vaccine from another manufacturer or with 2 or more doses of a prior formula of the Novavax COVID-19 vaccine are eligible to receive a single dose of the updated Novavax COVID-19 vaccine at least 2 months after the last dose of a COVID-19 vaccine.

In October 2024, The Advisory Committee on Immunization Practices (ACIP) recommended that all persons aged ≥65 years and persons aged 6 months–64 years with moderate or severe immunocompromise receive a second 2024–2025 COVID-19 vaccine dose 6 months after their last dose. Further, ACIP recommended that persons aged ≥6 months with moderate or severe immunocompromise may receive additional doses based on shared clinical decision-making.

As of October 31, 2024, the CDC has published updated Interim Clinical Considerations, including vaccine administration guidance by age group and previous COVID-19 vaccine history. In addition to this, the CDC has updated guidance on reporting vaccine adverse events and errors to the Vaccine Adverse Event Reporting System (VAERS) as well as a published Morbidity and Mortality Weekly Report (*MMWR)* addressing the updated COVID-19 vaccine recommendations from ACIP.

This technical bulletin summarizes the updated and simplified use of the updated 2024-2025 COVID-19 vaccines, including eligibility, doses and schedule. In all age groups, COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended; see Interchangeability of COVID-19 vaccines for circumstances in which doses from different manufacturers may be considered. Please note that an 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines. For detailed vaccination schedules, including age-appropriate vaccines, dosages, and intervals between doses, please visit CDC's comprehensive COVID-19 Vaccination Schedule Overview.

People who are not moderately or severely immunocompromised

Initial vaccination

Ages 6 months–4 years

- 2 doses of 2024–2025 Moderna or 3 doses of 2024–2025 Pfizer-BioNTech

Ages 5-11 years

- 1 dose of 2024–2025 Moderna or 1 dose of 2024–2025 Pfizer-BioNTech

Ages 12-64 years

- 1 dose of 2024–2025 Moderna or 1 dose of 2024–2025 Pfizer-BioNTech or 2 doses of 2024-2025 Novavax

Ages 65 years and older

- 2 doses of 2024–2025 Moderna or 2 doses of 2024–2025 Pfizer-BioNTech or 3 doses of 2024-2025 Novavax

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Received previous doses of a COVID-19 vaccine

Ages 6 months–4 years

- 1 or 2 doses of 2024–2025 mRNA vaccine from the same manufacturer as administered for initial vaccination, depending on the vaccine and the number of prior doses

Ages 5-11 years

- 1 dose of 2024–2025 Moderna or 1 dose of 2024–2025 Pfizer-BioNTech

Ages 12-64 years

- 1 dose of 2024–2025 Moderna or 1 dose of 2024–2025 Pfizer-BioNTech or 1 dose of 2024-2025 Novavax

Ages 65 years and older

- 2 doses of 2024–2025 Moderna or 2 doses of 2024–2025 Pfizer-BioNTech or 2 doses of 2024-2025 Novavax

People who are moderately or severely immunocompromised

Initial vaccination

Ages 6 months-4 years

- 3 doses of 2024–2025 Moderna or 3 doses of 2024–2025 Pfizer-BioNTech
    - Additional doses: Children who are moderately or severely immunocompromised, ages 6 months to 4 years, should receive 1 additional dose of 2024–2025 mRNA COVID-19 vaccine from the same manufacturer as the initial series 6 months after the last 2024–2025 mRNA vaccine dose. Any additional doses, beyond dose 4, may be administered under shared clinical decision-making at least 2 months after the last 2024-2025 mRNA vaccine dose.

Ages 5-11 years

- 3 doses of 2024–2025 Moderna or 3 doses of 2024–2025 Pfizer-BioNTech
    - Additional doses: Children who are moderately or severely immunocompromised, ages 5- 11 years, should receive 1 additional dose of 2024–2025 mRNA COVID-19 vaccine 6 months after the last 2024–2025 mRNA vaccine dose. Any additional doses, beyond dose 4, may be administered under shared clinical decision-making at least 2 months after the last 2024-2025 mRNA vaccine dose.

Ages 12 years and older

- 3 doses of 2024–2025 Moderna or 3 doses of 2024–2025 Pfizer-BioNTech or 2 doses of 2024-2025 Novavax
    - Additional doses: People who are moderately or severely immunocompromised, ages 12 years and older, should receive 1 additional dose of any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech, regardless of the manufacturer for the initial series) 6 months after the last 2024–2025 vaccine dose. Any additional doses, beyond dose 4, may be administered under shared clinical decision-making at least 2 months after the last 2024-2025 vaccine dose.

Received previous doses of a COVID-19 vaccine

- Recommended COVID-19 vaccine and number of 2024–2025 doses for people who are moderately or severely immunocompromised are based on age and vaccination history.

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Vaccine Information Fact Sheets & Prescribing Information

Pfizer-BioNTech's Vaccine Information Fact Sheets have been updated for Recipients and/or Caregivers and Healthcare Providers, which are available for reference.

Comirnaty Prescribing Information sheets are available for reference.

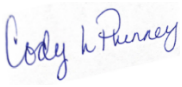
Moderna's Vaccine Information Fact Sheets have also been updated for Recipients and/or Caregivers and Healthcare Providers which are available for reference.

Spikevax Prescribing Information sheets are available for reference.

Novavax's Vaccine Information Fact Sheets have been updated for Recipients and/or Caregivers and Healthcare Providers, which are available for reference.

Questions

For updated guidance, review the Division of Public and Behavioral Health Technical Bulletin web page regularly. Email nviz@health.nv.gov for other questions regarding COVID-19 vaccination.



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