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Technical Bulletin

Date: **April 7, 2023**
Topic: **Bivalent COVID-19 Vaccines Now Authorized for Expansion in 6 months and Older**
Contact: **Jessica Lamb, RN, Nevada State Immunization Program**
To: **All Health Care Providers and Facilities; Pharmacists; Local Health Authorities**

Update:

On March 14, 2023, the U.S. Food and Drug Administration (FDA) amended the current Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide for a single booster dose of this bivalent vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with three doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine. This change only applies to the approximately 350,000 children who were early adopters of Pfizer's 3-dose COVID-19 vaccine primary series. However, this update means that all children in this age group are now eligible to receive an updated vaccine, either through completion of their primary series or through a booster dose. Following FDA action, on March 16, 2023, the Centers for Disease Control and Prevention (CDC) expanded its recommendation to allow children ages 6 months through 4 years who previously completed the full 3-dose monovalent Pfizer COVID-19 primary vaccination series to now receive a booster dose of Pfizer's updated (bivalent) COVID-19 vaccine.

Background:

On December 8, 2022, the U.S. Food and Drug Administration (FDA) issued amended Emergency Use Authorizations (EUAs) to both Moderna and Pfizer-BioNTech to authorize bivalent COVID-19 vaccines for children down to 6 months of age. The bivalent vaccines contain two messenger RNA (mRNA) components of SARS-CoV-2 virus; One of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2. The Moderna COVID-19 Vaccine, Bivalent has received authorization as a booster dose for individuals 6 months to 5 years and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent has received authorization as the third dose of the three-dose primary series for children 6 months to 4 years.

In addition, on December 8, 2022, **monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use as the third dose of the three-dose primary series in children 6 months through 4 years of age.** The monovalent Pfizer-BioNTech COVID-19 Vaccine remains authorized for administration as the first two doses of the three-dose primary series in individuals 6 months through 4 years of age, as a two-dose primary series for individuals 5 years of age and older, and as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise. Administration of monovalent Pfizer-BioNTech COVID-19 Vaccine used as the third dose of the three-dose primary series in children 6 months through 4 years of age are now considered vaccine administration errors and must be reported to the Vaccine Adverse Event Reporting System (VAERS).

This technical bulletin summarizes the recent Pfizer-BioNTech and Moderna Bivalent COVID-19 Vaccine eligibility. Vaccine products made by the same manufacturer should be used for all doses of the primary series.

Those eligible to receive the recommended **Pfizer-BioNTech COVID-19 Vaccine, Bivalent** include:

- **Any child ages 6 months to 4 years of age who has not yet begun their three-dose Pfizer primary series or has not yet received the third dose of their Pfizer primary series**
    - *Dose interval: A single bivalent dose administered as the third dose in the three-dose Pfizer primary series (two doses of the Pfizer monovalent, followed by one dose of Pfizer bivalent to complete the primary series).*
    - *Dose amount: 0.2mL each dose (*3 mcg/dose*), to be administered intramuscularly (*Please note that this product ***requires diluent***.)
- **UPDATED: Any child ages 6 months to 4 years of age who previously completed a 3-dose monovalent Pfizer-BioNTech primary series**
    - *Dose interval: A single bivalent booster dose administered at least two months following completion of Pfizer's age appropriate, monovalent vaccine primary series.*
    - *Dose amount: 0.2mL each dose (*3 mcg/dose*), to be administered intramuscularly (*Please note that this product ***requires diluent***.)

Those eligible to receive the recommended **Moderna COVID-19 Vaccine, Bivalent Booster** include:

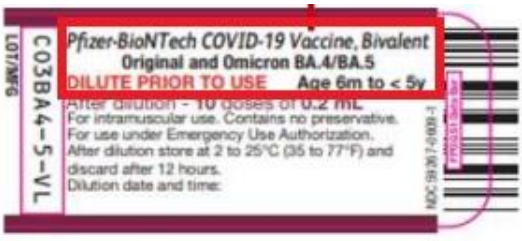
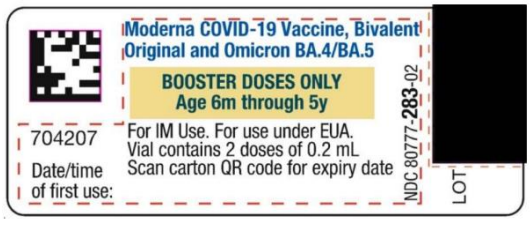
- **Any child ages 6 months to 5 years of age who has completed Moderna's monovalent COVID-19 vaccine primary series**
    - *Dose interval: a single booster dose administered at least **two** months following completion of Moderna's age appropriate, monovalent vaccine primary series.*
    - *Dose amount: 0.2mL each dose (*10 mcg/dose*), to be administered intramuscularly*

For more information and/or additional resources, the Centers for Disease Control and Prevention (CDC) has published updated interim clinical considerations and COVID-19 vaccine schedules for non-immunocompromised individuals and immunocompromised individuals. In addition, the CDC has also published a guide for "Special Situations for COVID-19 Vaccination of Children and Adolescents," which includes information on age transitions and COVID-19 vaccine interchangeability.

Pfizer-BioNTech's Vaccine Information Fact Sheets for Recipients and/or Caregivers and Healthcare Providers are available for reference, in addition to a Letter to Healthcare Providers.

Moderna's Vaccine Information Fact Sheets for Recipients and/or Caregivers and Healthcare Providers are available for reference, in addition to a Letter to Healthcare Providers.

Both Pfizer-BioNTech and Moderna's COVID-19 Bivalent Vaccines, for this age group, are new COVID-19 products with some different storage and handling parameters than other COVID-19 products. Pfizer-BioNTech COVID-19 Vaccine, Bivalent (6 months – 4 years) is packaged in 10-dose vials in cartons of 10 vials each (100 doses total) and will ***require diluent***. Moderna's COVID-19 Vaccine, Bivalent booster (ages 6 months – 5 years) be packaged in **2-dose vials** in cartons of 10 vials each (20 doses total). Additional storage and handling parameters include:

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling	Moderna COVID-19 Vaccine Storage and Handling
REQUIRES DILUENT (2.2mL diluent/per vial)	Does NOT require diluent
Ultra-cold freezer storage (-90°C to -60°C) until expiry	NO ULTRA-COLD FREEZER STORAGE
No freezer storage	Freezer storage (-25°C to -15°C) until expiry
Refrigerate (2°C to 8°C) up to 10 weeks without puncturing	Refrigerate (2°C to 8°C) up to 30 days without puncturing
Once punctured, vial must be used within **12 hours**	Once punctured, vial must be used within 8 **hours**
Vial/Label Color: Maroon Cap with Maroon border *(Please note that the cap and vial border colors are **identical** for both Pfizer's monovalent and bivalent formulations for 6 months – 4 years. Vial label will specifically say "Bivalent" on it to differentiate between the two.)*	Vial/Label Color: Dark Pink Cap with Yellow Box Label
Under 5 Bivalent Vaccine Vial (6 months – 4 years):  **Under 5 Bivalent Vaccine Label (6 months – 4 years):** 	**Under 5 Bivalent Booster Vial (6 months – 5 years):**  **Under 5 Bivalent Booster Label (6 months – 5 years):** 

It is important to note the primary goal of the COVID-19 vaccine response should continue to be COVID-19 vaccine administration to the unvaccinated. The Nevada Department of Health and Human Services is encouraging individuals to speak with a health care provider about vaccination and COVID-19 vaccines. Individuals may be referred to NVCOVIDFighter.org for more information on vaccine access and other COVID-19 resources.

Questions:
For updated guidance, review the DPBH Technical Bulletin web page regularly. Email questions to dpbhcovid19vax@health.nv.gov.

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