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DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

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Lisa Sherych
Administrator

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

Technical Bulletin

Date: **September 9, 2022**
Topic: **Bivalent COVID-19 Booster Vaccine Recommended for 12 Years and Older**
Contact: **Jessica Lamb, RN, Nevada State Immunization Program**
To: **All Health Care Providers and Facilities; Pharmacists; Local Health Authorities**

Background:

On August 31, 2022, the U.S. Food and Drug Administration (FDA) issued amended Emergency Use Authorizations (EUAs) to both Moderna and Pfizer-BioNTech to authorize their bivalent formulations of the COVID-19 vaccine for use as a single booster dose at least two months following primary or booster vaccination. 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 formulation is authorized in individuals 18 years of age and older, and the Pfizer-BioNTech COVID-19 vaccine bivalent formulation is authorized in individuals 12 years of age and older.

In addition, as of August 31, 2022, **all monovalent mRNA COVID-19 vaccines are no longer authorized by the FDA as booster doses for individuals 12 years of age and older.** Administration of any monovalent booster vaccines for individuals 12 years of age and older is now considered a vaccine administration error and must be reported to the Vaccine Adverse Event Reporting System (VAERS).

With the evidence presented at the Sept. 1, 2022, meeting of the Advisory Committee on Immunization Practices (ACIP), the committee voted in favor to recommend a single dose of bivalent formulation of the Pfizer-BioNTech COVID-19 vaccine for individuals ages 12 years and older, and a single dose of bivalent formulation of the Moderna COVID-19 vaccine for individuals ages 18 years and older — both at least two months after receipt of a primary series or prior monovalent booster dose under the EUA issued by the FDA. In addition, the ACIP voted to repeal its previous recommendations for administration of a monovalent Pfizer-BioNTech COVID-19 vaccine booster for persons ages 12 years and older and of a monovalent Moderna COVID-19 vaccine booster for persons ages 18 years and older.

This technical bulletin summarizes the recent Pfizer-BioNTech and Moderna bivalent COVID-19 booster vaccine eligibility. *At this time*, the single-dose COVID-19 bivalent booster vaccines are not authorized to be used as a primary series and are only available to individuals who have completed a COVID-19 primary vaccine series, regardless of the number or type of booster doses received/administered prior.

Persons eligible to receive the recommended **Pfizer-BioNTech COVID-19 bivalent formulation booster vaccine** include:

- **Any individual 12 years of age or older who has completed a COVID-19 primary vaccine series.**
    - *Dose interval: a single booster dose administered at least **two** months following completion of any COVID-19 vaccine primary series and/or previous booster dose.*
    - *Dose amount: 0.3m L each dose (containing 15 mcg original SARS-CoV-2 and 15mcg Omicron BA.4/BA.5), to be administered intramuscularly.*

Persons eligible to receive the recommended **Moderna COVID-19 bivalent booster vaccine** include:

- **Any individual 18 years of age or older who has completed a COVID-19 primary vaccine series.**
    - *Dose interval: a single booster dose administered at least **two** months following completion of any COVID-19 vaccine primary series and/or previous booster dose.*
    - *Dose amount: 0.5 mL each dose (containing 25 mcg original SARS-CoV-2 and 25mcg Omicron BA.4/BA.5), to be administered intramuscularly.*

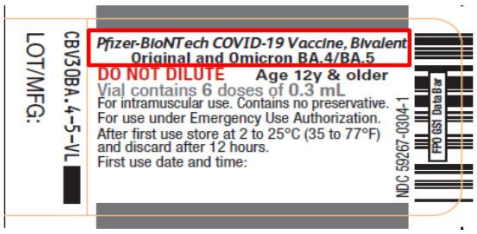
Both Pfizer-BioNTech and Moderna's COVID-19 bivalent booster vaccines will have the same storage and handling parameters as their original vaccine products. The Pfizer-BioNTech COVID-19 bivalent booster vaccine is expected to be packaged in six-dose vials in cartons of 10 vials each (60 doses total); the Moderna COVID-19 bivalent booster vaccine will be packaged in five-dose vials in cartons of 10 vials each (50 doses total). Once punctured, each vial must be used within ***12 hours***. Similar to existing Moderna and Pfizer-BioNTech (grey cap) products, vials must be discarded no more than 12 hours after the first puncture. Additional storage and handling parameters are outlined in the chart on page 3.

The primary goal of the COVID-19 vaccine response should continue to be COVID-19 vaccine administration to unvaccinated individuals. 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 or 1-800-401-0946 for more information on vaccine access and other COVID-19 resources.

For more information and/or additional resources, the Centers for Disease Control and Prevention (CDC) has published updated COVID-19 vaccine interim clinical considerations, COVID-19 Vaccination Clinical & Professional Resources and At-A-Glance COVID-19 Vaccination Schedule.

Pfizer-BioNTech's Vaccine Information Fact Sheets on Bivalent Boosters for Recipients and/or Caregivers and Healthcare Providers have also been updated by the FDA for reference.

Moderna's Vaccine Information Fact Sheets on Bivalent Boosters for Recipients and/or Caregivers and Healthcare Providers have also been updated by the FDA for reference, in addition to a Letter to Healthcare Providers.

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling	Moderna COVID-19 Vaccine Storage and Handling
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
Bivalent Booster Vial:  **Bivalent Booster Label:**  	**Bivalent Booster Vial:**  **Bivalent Booster Label:** 

Questions: For updated guidance, visit the [Division of Public and Behavioral Health Technical Bulletin web page] and the [Nevada Health Response website] regularly. Email questions to [dpbhcovid19vax@health.nv.gov].

Lisa Sherych, Administrator
Division of Public and Behavioral Health

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer