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DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
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Technical Bulletin

Date: October 19, 2022
Topic: Bivalent COVID-19 Booster Vaccine Recommended for 5 Years and Older
Contact: Jessica Lamb, RN, Nevada State Immunization Program
To: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

Background:

On October 12, 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 pediatric 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 from 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 for pediatric individuals 6-11 years of age and the [Pfizer-BioNTech COVID-19 Vaccine, Bivalent](#) has received authorization for pediatric individuals 5-11 years of age. In addition to these pediatric authorizations, Moderna's current COVID-19 bivalent booster now has extended authorization to those individuals 12 years of age and older (it was previously only authorized for individuals 18+ years).

In addition, on October 12, 2022, **Pfizer-BioNTech's monovalent mRNA COVID-19 vaccine is no longer authorized by the FDA to be administered as a booster dose for pediatric individuals 5-11 years of age.** This now means that the recently approved bivalent booster vaccines are the only authorized booster formulations available for administration. All COVID-19 monovalent formulation vaccines may ONLY be administered as a primary series, NOT as booster dose to any individuals, regardless of their age. Administration of any monovalent booster vaccines for individuals 5+ years are now considered vaccine administration errors and must be reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

At the most recent [Advisory Committee on Immunization Practices \(ACIP\)](#) meeting and [Vaccines and Related Biological Products Advisory Committee \(VRBPAC\)](#) meeting, [evidence and data](#) was presented and discussed on this matter. 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 5+ years who have completed an [FDA authorized 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, pediatric bivalent formulation booster vaccine** include:

- **Any pediatric individual ages 5-11 years who has completed a COVID-19 primary vaccine series**
 - Dose interval: a single booster dose administered at least two months following completion of any age appropriate, FDA authorized COVID-19 vaccine primary series and/or previous booster dose
 - Dose amount: 0.2mL each dose (10 µg/dose), to be administered intramuscularly (Please note that this product **requires diluent.**)

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

- **Any pediatric individual ages 6-11 years who has completed a COVID-19 primary vaccine series**
 - *Dose interval: a single booster dose administered at least two months following completion of any age appropriate, FDA authorized COVID-19 vaccine primary series and/or previous booster dose*
 - *Dose amount: 0.25mL each dose (25 µg/dose), to be administered intramuscularly*

UPDATED AGE RECOMMENDATION FOR ADULT DOSING OF MODERNA BIVALENT BOOSTER:

Those now eligible to receive the recommended **Moderna COVID-19, bivalent 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 age appropriate, FDA authorized COVID-19 vaccine primary series and/or previous booster dose*
 - *Dose amount: 0.5mL each dose (50 µg/dose), to be administered intramuscularly*


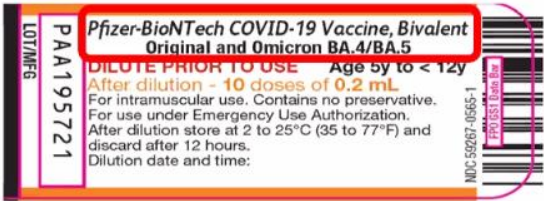

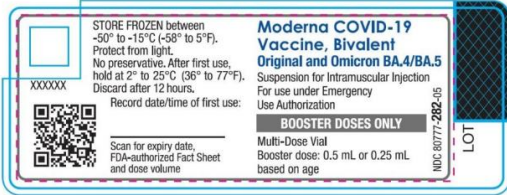
Both Pfizer-BioNTech and Moderna's COVID-19 Bivalent booster vaccines will have the same [storage and handling](#) parameters as their original/other bivalent vaccine products. Pfizer-BioNTech Pediatric COVID-19 Bivalent booster vaccine (ages 5-11years) is expected to be packaged in 10-dose vials in cartons of 10 vials each (100 doses total) and will require diluent. Moderna's Pediatric COVID-19 Bivalent booster vaccine (ages 6-11 years) will use the same vial formulation as the 12+ vials, except the 6-11year dose (.25mL) will be half the amount of the 12+ dose (0.5mL). Moderna's COVID-19 Bivalent booster vaccine will continue to be packaged in 5-dose vials in cartons of 10 vials each (50 doses total for 12+ use, 100 doses total for 6-11 use). Once punctured, both Pfizer and Moderna's bivalent booster vials, must be used within **12 hours**. Similar to existing Moderna and Pfizer-BioNTech (grey cap) products, vials must be discarded ≤12 hours after the first puncture. Additional storage and handling parameters are outlined in the chart on page 3.

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 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 and Professional Resources](#) and COVID-19 vaccine schedules for [non-immunocompromised individuals](#) and [immunocompromised individuals](#).

Pfizer-BioNTech's Vaccine Information Fact Sheets for [Recipients and/or Caregivers](#) and [Healthcare Providers](#) have also been updated by the FDA for reference.

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](#).

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling	Moderna COVID-19 Vaccine Storage and Handling
Requires diluent (1.3mL diluent/per vial)	Does <i>not</i> 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
<p align="center">Pediatric Bivalent Booster Vial (5-11 years):</p>  <p align="center">Bivalent Booster Label:</p> 	<p align="center">Pediatric (6-11 years) & 12+ Bivalent Booster Vial:</p>  <p align="center">Bivalent Booster Label:</p> 

Questions:

For updated guidance, please review the [DPBH Technical Bulletin web page](#) and the [Nevada Health Response website](#) regularly. Email questions to dpbh-covid19vax@health.nv.gov.



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