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TECHNICAL BULLETIN

Date: May 11, 2023
Topic: FDA Ends Monovalent mRNA Authorization and Simplifies Use of Bivalent COVID-19 Vaccines
Contact: Jessica Lamb, RN, Nevada State Immunization Program
To: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

Background:
On April 18, 2023, the U.S. Food and Drug Administration (FDA) issued amended Emergency Use Authorizations (EUAs) to both Moderna and Pfizer-BioNTech to simplify the COVID-19 bivalent mRNA vaccine schedule for most individuals. Included in this authorization, bivalent vaccines are to be used for all doses administered to individuals 6 months of age and older, as well as an additional dose or doses for certain populations. The mRNA bivalent COVID-19 vaccines currently available contain 2 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.

In addition, on April 18, 2023, all monovalent Moderna and Pfizer-BioNTech mRNA COVID-19 vaccines are no longer authorized for use in the United States, regardless of age. Administration of any monovalent Moderna or Pfizer-BioNTech mRNA COVID-19 vaccines are now considered vaccine administration errors and must be reported to the Vaccine Adverse Event Reporting System (VAERS).

On April 19, 2023, the Advisory Committee on Immunization Practices (ACIP) (ACIP) members expressed their support for these recommendations. The Centers for Disease Control and Prevention (CDC) and ACIP will continue to monitor COVID-19 disease levels and vaccine effectiveness in the months ahead and look forward to additional discussion around potential updates this fall.

This technical bulletin summarizes the updated and simplified use of both Pfizer-BioNTech and Moderna's Bivalent COVID-19 vaccines, including eligibility and schedule. Currently, *non-immunocompromised individuals who have already received a single dose of the bivalent vaccine are not eligible for another bivalent COVID-19 dose*. For those individuals who are moderately to severely immunocompromised, please see CDC's COVID-19 Interim Clinical Considerations for specific vaccine guidance and schedules.

Those eligible to receive a dose of Pfizer-BioNTech Bivalent COVID-19 vaccine include:

- Individuals 6 months of age and older who have not previously been vaccinated with a COVID-19 vaccine (by age group)
  6 months – 4 years (maroon vial cap):
  - *Dose interval: Three bivalent doses administered (Dose 1: Week 0, Dose 2: Week 3-8*, Dose 3: ≥ 8 weeks after dose 2)*
  - *Dose amount: 0.2mL each dose (*3 mcg/dose*), to be administered intramuscularly*

  5 -11 years (orange vial cap):
  - *Dose interval: A single bivalent dose administered*
  - *Dose amount: 0.2mL each dose (*10 mcg/dose*), to be administered intramuscularly*

  12-64 years (gray vial cap):

- *Dose interval:* *A single bivalent dose administered*
- *Dose amount:* *0.3mL each dose (30 mcg/dose), to be administered intramuscularly*

65+ years (gray vial cap):

- *Dose interval:* *A single bivalent dose administered (One additional dose may be administered ≥ 4 months after first dose of an authorized bivalent COVID-19 vaccine)*
- *Dose amount:* *0.3mL each dose (30 mcg/dose), to be administered intramuscularly*

- Individuals 6 months through 4 years of age who have previously been vaccinated with the monovalent Pfizer-BioNTech COVID-19 vaccine (by number of previous Pfizer-BioNTech doses)

  1 previous dose:
  - *Dose interval:* *Two bivalent Pfizer-BioNTech doses administered (Dose 1: 3-8 weeks* after receipt of a Pfizer-BioNTech COVID-19 vaccine, Dose 2: ≥ 8 weeks after dose 1)*
  - *Dose amount:* *0.2mL each dose (3 mcg/dose), to be administered intramuscularly*

  2 previous doses:
  - *Dose interval:* *A single bivalent dose administered ≥ 8 weeks after receipt of second dose of a Pfizer-BioNTech COVID-19 vaccine*
  - *Dose amount:* *0.2mL each dose (3 mcg/dose), to be administered intramuscularly*

  3 previous doses:
  - *Dose interval:* *A single bivalent dose administered ≥ 8 weeks after receipt of third dose of a Pfizer-BioNTech COVID-19 vaccine*
  - *Dose amount:* *0.2mL each dose (3 mcg/dose), to be administered intramuscularly*

- Individuals 5 years of age and older who have previously been vaccinated with one (1) or more doses of any monovalent COVID-19 vaccine (by age group)

  5 -11 years (orange vial cap):
  - *Dose interval:* *A single bivalent dose administered ≥ 8 weeks after receipt of a monovalent COVID-19 vaccine*
  - *Dose amount:* *0.2mL each dose (10 mcg/dose), to be administered intramuscularly*

  12-64 years (gray vial cap):
  - *Dose interval:* *A single bivalent dose administered ≥ 8 weeks after receipt of a monovalent COVID-19 vaccine*
  - *Dose amount:* *0.3mL each dose (30 mcg/dose), to be administered intramuscularly*

  65+ years (gray vial cap):
  - *Dose interval:* *A single bivalent dose administered ≥ 8 weeks after receipt of a monovalent COVID-19 vaccine (One additional dose may be administered ≥ 4 months after first dose of an authorized bivalent COVID-19 vaccine)*
  - *Dose amount:* *0.3mL each dose (30 mcg/dose), to be administered intramuscularly*

Those eligible to receive a dose of Moderna Bivalent COVID-19 vaccine include:

- Individuals 6 months of age and older who have not previously been vaccinated with a COVID-19 vaccine (by age group)

  6 months – 5 years (dark blue cap with gray label border):
  - *Dose interval:* *Two bivalent doses administered (Dose 1: Week 0, Dose 2: 4-8 weeks* after dose 1)*
  - *Dose amount:* *0.25mL each dose (25 mcg/dose), to be administered intramuscularly*

  6 -11 years (dark blue cap with gray label border):
  - *Dose interval:* *A single bivalent dose administered*
  - *Dose amount:* *0.25mL each dose (25 mcg/dose), to be administered intramuscularly*

  12-64 years (dark blue cap with gray label border):
  - *Dose interval:* *A single bivalent dose administered*
  - *Dose amount:* *0.5mL each dose (50 mcg/dose), to be administered intramuscularly*

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65+ years (dark blue cap with gray label border):
    - *Dose interval: A single bivalent dose administered (One additional dose may be administered ≥ 4 months after first dose of an authorized bivalent COVID-19 vaccine)*
    - *Dose amount: 0.5mL each dose (*50 mcg/dose*), to be administered intramuscularly*

- Individuals 6 months through 5 years of age who have previously been vaccinated with Moderna COVID-19 vaccine(s) (by number of previous Moderna doses)
  1 previous dose (dark blue cap with gray label border):
    - *Dose interval: A single bivalent dose administered 4-8 weeks* after receipt of a Moderna COVID-19 vaccine*
    - *Dose amount: 0.25mL each dose (*25 mcg/dose*), to be administered intramuscularly*
  2 previous doses (dark pink cap with yellow box label):
    - *Dose interval: A single bivalent dose administered ≥ 8 weeks after receipt of a Moderna COVID-19 vaccine*
    - *Dose amount: 0.2mL each dose (*10 mcg/dose*), to be administered intramuscularly*

- Individuals 6 years of age and older who have previously been vaccinated with one (1) or more doses of any monovalent COVID-19 vaccine (by age group)
  6 -11 years (dark blue cap with gray label border):
    - *Dose interval: A single bivalent dose administered ≥ 8 weeks after receipt of a monovalent COVID-19 vaccine*
    - *Dose amount: 0.25mL each dose (*25 mcg/dose*), to be administered intramuscularly*
  12-64 years (dark blue cap with gray label border):
    - *Dose interval: A single bivalent dose administered ≥ 8 weeks after receipt of a monovalent COVID-19 vaccine*
    - *Dose amount: 0.5mL each dose (*50 mcg/dose*), to be administered intramuscularly*
  65+ years (dark blue cap with gray label border):
    - *Dose interval: A single bivalent dose administered ≥ 8 weeks after receipt of a monovalent COVID-19 vaccine (One additional dose may be administered ≥ 4 months after first dose of an authorized bivalent COVID-19 vaccine)*
    - *Dose amount: 0.5mL each dose (*50 mcg/dose*), to be administered intramuscularly*

*An 8-week interval between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

For more information and/or additional resources, the Centers for Disease Control and Prevention (CDC) has published updated interim clinical considerations, including specific vaccine guidance and schedules for those individuals who are moderately to severely immunocompromised. In addition, the CDC has also updated their COVID-19 vaccine webpages and Interchangeability of COVID-19 vaccines.

For those individuals who are moderately to severely immunocompromised, please see CDC's COVID-19 Interim Clinical Considerations for specific vaccine guidance and schedules, by age. People who are or who become moderately or severely immunocompromised should follow the COVID-19 vaccination schedule according to their age and immune status at the time of eligibility for that dose; see Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies for vaccination of people who will shortly become moderately or severely immunocompromised (e.g., prior to organ transplant) and Considerations for COVID-19 revaccination.

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Pfizer-BioNTech's Vaccine Information Fact Sheets have been updated for Recipients and/or Caregivers and Healthcare Providers, which 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, in addition to a Letter to Healthcare Providers.

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 Division of Public and Behavioral Health Technical Bulletin web page regularly. Email dpbhcovid19vax@health.nv.gov for other questions.

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