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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

CDC and FDA Authorize COVID19 Bivalent Vaccine for Boosters

September 5, 2022

Background:

On August 31, 2022, the FDA authorized emergency use of new **bivalent formulations** of both the Moderna COVID-19 and the Pfizer-BioNTech COVID-19 Vaccines for use as a single booster dose at least two months following primary or booster vaccination. The Advisory Committee on Immunization Practices (ACIP) voted on September 1, 2022, to recommend the updated vaccines and the CDC endorsed the ACIP recommendations the same day. This authorization follows the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) June vote to include a BA.4/BA.5 omicron component in COVID-19 booster vaccines.

The bivalent vaccines, also referred to as the "updated vaccine" or "Omicron boosters," contain both the original vaccines as well as components from the omicron BA.4/BA.5 variants. The bivalent boosters will bolster immunity, specifically targeting the more transmissible and immune-evading BA.4/BA.5 omicron subvariants which are currently causing most cases of COVID-19 and are predicted to continue to circulate this fall and winter.

The Moderna COVID-19 Vaccine, Bivalent, is authorized for use as a **single booster dose** in individuals 18 years of age and older. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent, is authorized for use as a **single booster dose** in individuals 12 years of age and older.

As of 8/31/22, the FDA removed authorization for the original (monovalent) COVID-19 mRNA vaccines to be used for booster doses in people 12 years and older, although they are still indicated for the primary vaccine series.

Eligibility for the Bivalent Boosters:

- Individuals 18 years of age and older are eligible for a single booster dose of the Moderna COVID-19 Vaccine, Bivalent, if it has been at least two months since they have completed primary vaccination or have received a booster dose with any authorized or approved monovalent COVID-19 vaccine.
- Individuals 12 years of age and older are eligible for a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, if it has been at least two months since they have completed primary vaccination or have received a booster dose with any authorized or approved monovalent COVID-19 vaccine.
- This new booster recommendation replaces all prior booster recommendations for people 12 and older with immune compromise. People with immune compromise should complete a 3 dose primary series with a monovalent mRNA vaccine prior to receiving an age-

appropriate bivalent booster.

- This booster recommendation replaces all prior booster recommendations for people 12 and older who have started a vaccine series outside the US with a WHO authorized but not FDA approved/authorized monovalent vaccine.

Moderna COVID-19 Vaccine, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)

- The Moderna Bivalent Vaccine is authorized for individuals 18 years and older as a single booster dose given at least 2 months after:
 - completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine (Pfizer, Moderna, Novavax, Janssen), OR
 - receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- The Moderna Bivalent vaccine dose is 50 µg (0.5cc) and is given intramuscularly (IM).
- This formulation is in a vial with a **dark blue cap** and **grey label border** (NDC: 80777-0282-99).

Pfizer COVID-19 Vaccine, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)

- The Pfizer Bivalent Vaccine is authorized for individuals 12 years and older as a single booster dose given at least 2 months after:
 - completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine (Pfizer, Moderna, Novavax, Janssen), OR
 - receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- The Pfizer Bivalent vaccine dose is 30 µg (0.3cc) and is given IM.
- This formulation is in a vial with a **grey cap** and **grey label border** (NDC: 59267-0304-02) and is distinguishable from the monovalent adult grey cap Pfizer vaccine only by noting “Bivalent” on the label. Careful attention is needed to avoid confusing these two products.
- The Pfizer-BioNTech COVID-19 Vaccine (**orange cap**) remains authorized for a single booster dose for individuals 5 through 11 years of age at least five months after completing a primary series of the Pfizer-BioNTech COVID-19 Vaccine.

Safety Considerations:

- Based on the overall data to date, the risk for myocarditis and pericarditis after an mRNA COVID-19 booster dose in adolescents and young adults appears generally similar to or lower than the risk after a second mRNA COVID-19 vaccine primary series dose.
- The side effect profile of the updated vaccines appears to be similar to that of the monovalent vaccines. Among the study participants who received the bivalent vaccine (ancestral/BA.1), the most reported side effects included pain, redness and swelling at the injection site, fatigue, headache, muscle pain, joint pain, chills, swelling of the lymph nodes in the same arm of the injection, nausea/vomiting, and fever.
- The evidence supporting each bivalent COVID-19 vaccine includes extensive safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines, safety and immunogenicity data obtained from a clinical study of a bivalent COVID-19 vaccine that contained mRNA from omicron variant BA.1, and nonclinical data obtained using a bivalent COVID-19 vaccine that contained mRNA of the original strain and mRNA in common between the BA.4 and BA.5 lineages of the omicron variant.

EPIDEMIOLOGY AND RESPONSE

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Additional Considerations:

1. **Primary Series vs. Bivalent Booster:** The monovalent (original) COVID-19 vaccines should still be administered for the primary series; the bivalent formulations are not authorized for the primary series.
2. **Up to date status:** CDC's currently defines "up to date" with COVID-19 vaccine as having completed a COVID-19 vaccine primary series and having received the most recent booster dose recommended for you by CDC (i.e. the bivalent booster for anyone 12 and older).
3. **Recommendations for People with Immune Compromise:** For people with immune compromise, the primary series consists of 3 doses of an mRNA vaccine.
4. **Co-administration of Vaccine:**
 - COVID-19 vaccines may be administered without regard to timing of other vaccines.
 - Flu vaccine can be administered at the same time as COVID-19 vaccines.
 - Adolescent and young men may consider waiting to get COVID-19 vaccine until four weeks after orthopox vaccine because of the unknown risk for myocarditis and pericarditis associated with JYNNEOS. If orthopox vaccine is given for prophylaxis, no minimum interval is necessary.

Access to Bivalent Boosters:

- New Mexico COVID-19 vaccine providers can immediately implement the above recommendations.
- Providers can order the bivalent boosters in NMSIIS starting Tuesday, September 6, 2022.
- The statewide registration app has been updated for bivalent booster scheduling and can be accessed using vaccinenm.org. People can also schedule directly with their medical and pharmacy providers.
- Once vaccines are available, vaccine appointments can also be found on the CDC Vaccine Finder website: [Vaccines.gov - Find COVID-19 vaccine locations near you](https://www.cdc.gov/vaccines/imz/finding-locations/).
- All providers are encouraged to provide office-based COVID-19 vaccines and boosters.

Additional Resources:

1. Clinical recommendations from CDC are updated here: [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](https://www.cdc.gov/media/releases/2022/s0906-covid-19-vaccines.html)
2. All COVID-19 Vaccine fact sheets are accessible here: [Coronavirus Disease 2019 \(COVID-19\) | FDA](https://www.fda.gov/covid-19/coronavirus-disease-2019-covid-19)
3. For clinicians wishing to administer COVID-19 vaccine, please contact the NM DOH Immunization Team at covid.vaccines@state.nm.us or find more information at: [Immunization Education & Tools for Healthcare Providers \(nmhealth.org\)](https://www.nmhealth.org/immunization)

New Mexico Health Alert Network: To register for the New Mexico Health Alert Network, click the following link to go directly to the HAN registration page <https://nm.readyop.com/fs/4cjz/10b2> Please provide all information requested to begin receiving important health alerts and advisories.