



MICHELLE LUJAN GRISHAM  
Governor

DAVID R. SCRASE, M.D.  
Acting Cabinet Secretary

## NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

### CDC and FDA Authorize COVID19 Bivalent Vaccine for Youngest Children

December 12, 2022

#### Background:

On December 8, 2022, the FDA authorized emergency use of the **bivalent formulations** of both the Moderna COVID-19 and the Pfizer-BioNTech COVID-19 Vaccines to include children ages 6 months to 5 years of age. The CDC endorsed the decision the following day.

Children ages 6 months through 5 years who previously completed a Moderna primary series are eligible to receive a Moderna bivalent booster 2 months after completion of their primary series. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent, for ages 6 months through 4 years old, is authorized for use as *the third dose* in the three dose primary series.

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. New data shows the updated bivalent COVID vaccines provide additional protection against COVID-19, bolster immunity and are more effective against current Omicron sub-variants than the original monovalent vaccine.<sup>1</sup>

#### Moderna COVID-19 Vaccine, BIVALENT (ORIGINAL ANDOMICRON BA.4/BA.5) for ages 6 month – 5 years

- The Moderna Bivalent Vaccine is authorized for individuals 6 months through 5 years as a single booster dose given at least 2 months after completion of the primary Moderna vaccination.
- The Moderna Bivalent vaccine dose for children ages 6 months to 5 years is 10 µg (0.2 mL) and is given intramuscularly (IM).
- This formulation is in a vial with a **dark pink cap** and a label with a yellow box (NDC: **80777-0283-99**).
- Only the Moderna bivalent booster is authorized for children ages 6 months through 4 years old who complete a Moderna primary series. Children who are 5 years old can receive either the age-appropriate Pfizer or the Moderna bivalent boosters.

#### Pfizer COVID-19 Vaccine, BIVALENT (ORIGINAL ANDOMICRON BA.4/BA.5) for ages 6 months – 4 years

- This Pfizer Bivalent Vaccine is authorized for children ages 6 months to 4 years as the third dose in the 3 dose primary series and is given at least 8 weeks after the second dose.

---

<sup>1</sup> [Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection — Increasing Community Access to Testing Program, United States, September–November 2022 | MMWR \(cdc.gov\)](#)

- The same schedule applies for children in this age group who are immunocompromised.
- The vaccine dose for this formulation is 3 µg (0.2 mL) and is given IM.
- This formulation is in a vial with a **maroon cap** (NDC: 59267-0078-04) and is distinguishable from the monovalent product by noting “Bivalent” on the label.
- If children in this age group have already completed their three-dose primary series with the monovalent Pfizer vaccine, they are not eligible for a bivalent booster dose at this time. They are still expected to have high levels of immunity. The data to support giving an updated bivalent booster dose for these children are expected in January.

#### **Safety Considerations:**

- The side effect profile of the updated vaccines is similar to that of the monovalent vaccines.
- 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.

#### **Additional Considerations:**

1. **Up to date status:** Individuals are “up to date” with COVID-19 vaccine if they have completed a COVID-19 vaccine primary series and have received the most recent booster dose recommended (i.e., the bivalent vaccine for anyone 6 months and older).
2. **Recommendations for People with Immune Compromise:** For people with immune compromise, the primary series consists of 3 doses of an mRNA vaccine.
3. **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.

#### **Access to Bivalent Boosters:**

- New Mexico COVID-19 vaccine providers can immediately implement the above recommendations.
- Providers can now order the bivalent boosters for this age group in NMSIIS.
- The statewide registration app has been updated for scheduling and can be accessed using [vaccinenm.org](https://vaccinenm.org). People can also schedule directly with 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/s0927-covid-19-vaccines.html)
2. Access COVID-19 Vaccine fact sheets here: [Coronavirus Disease 2019 \(COVID-19\) | FDA](https://www.fda.gov/covid19/coronavirus-disease-2019-covid-19)

#### **EPIDEMIOLOGY AND RESPONSE**

1190 St. Francis Drive, N1320 • Santa Fe, New Mexico • 87502-6110  
(505) 827-0006 • FAX: (505) 827-2110 • [www.nmhealth.org](http://www.nmhealth.org)



MICHELLE LUJAN GRISHAM  
Governor

DAVID R. SCRASE, M.D.  
Acting Cabinet Secretary

3. For clinicians wishing to administer COVID-19 vaccine, please contact the NM DOH Immunization Team at [covid.vaccines@state.nm.us](mailto:covid.vaccines@state.nm.us) or find more information at: [Immunization Education & Tools for Healthcare Providers \(nmhealth.org\)](https://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.***