

# What Providers Need to Know about Monovalent COVID-19 Vaccines: Pfizer-BioNTech



National Association of  
Pediatric Nurse Practitioners<sup>SM</sup>  
Immunization SIG

*COVID-19 vaccines will be covered under Vaccines for Children*

## Product Overview

Monovalent XBB.1.5 BNT162b2 Vaccine Activity Against Contemporary Omicron Sublineages

Monovalent XBB.1.5 BNT162b2 is equally immunogenic against XBB.1.5, EG.5.1 and BA.2.86, in a COVID-19 vaccine-experienced preclinical study

- **SE: 6 months through 23 months of age:** injection site redness; swelling and tenderness; decreased appetite; drowsiness; fever; irritability • **2 through 11 years of age:** injection site pain; redness and swelling; chills; diarrhea; fatigue; fever; headache; new or worsened joint pain; new or worsened muscle pain; vomiting
- Safety and immunogenicity same across ages
- Data from Female Balb/c mice (10 per group) were administered 2 doses (21 days apart) of either bivalent BNT162b2 (Original+BA.4/5) or monovalent BNT162b2 (XBB.1.5) vaccine. Data were generated by the same pseudovirus neutralization assay and from sera of the same mouse study presented at VRBPAC June 15, 2023 meeting.
- Results of clinical study to come out 4th Quarter 2023 for >12 years N:400 with single dose

## Administration

The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is authorized/approved for all doses administered to individuals 6 months and older to prevent COVID-19. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is no longer authorized for use in the United States. Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is authorized for use as follows:

### Individuals 6 months through 4 years of age:

0.3ml of multi-dose vials (after dilution 3 doses per vial)

- Unvaccinated individuals: Three doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) are administered. The first two doses are administered three weeks apart. The third dose is administered at least 8 weeks after the second dose.
- Individuals who have received one dose of any Pfizer BioNTech COVID-19 Vaccine, including Pfizer-BioNTech COVID-19 Vaccine, Bivalent: Two doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) are administered. The first dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is administered three weeks after receipt of the previous dose and the second dose is administered at least 8 weeks later.
- Individuals who have received two to four doses of any Pfizer BioNTech COVID-19 Vaccine, including Pfizer-BioNTech COVID-19 Vaccine, Bivalent: A single dose of Pfizer-BioNTech COVID 19 Vaccine (2023-2024 Formula) is administered at least 8 weeks after receipt of the last previous dose.
- For children 6 months to 4 years of age COVID vaccines should NOT be interchanged.

### Individuals 5 years through 11 years of age, regardless of vaccination status:

0.3ml single dose vial

- Single dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula). If previously vaccinated with any COVID-19 vaccine, administer at least 2 months after receipt of the last previous dose of any COVID-19 vaccine.

### Immunocompromised individuals 6 months through 11 years of age

- Complete at least a three-dose series with a COVID-19 vaccine, each dose one month apart. At least one dose should be with a COVID-19 vaccine (2023-2024 Formula).

### Individuals 12 and older

0.3ml single dose vial or pre-filled syringes

- COMIRNATY® (COVID-19 Vaccine, mRNA) (2023-2024 Formula) approved

## Resources

- [C4591020 Results Review \(cdc.gov\)](https://www.cdc.gov/vaccines/imz-managers/decision-support/assessing-uptake/assessing-uptake-covid-19-vaccine.html)
- [Pfizer-BioNTech COVID-19 Vaccine | FDA](https://www.fda.gov/oc/2023/06/15/pfizer-biontech-covid-19-vaccine)