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

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)
- Pfizer-BioNTech COVID-19 Vaccine | FDA