



TO: West Virginia Healthcare Providers, Hospitals and Other Healthcare Facilities

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LOCAL HEALTH DEPARTMENTS: Please distribute to community health providers, hospital-based physicians, infection control preventionists, laboratory directors and other applicable partners.

OTHER RECIPIENTS: Please distribute to association members, staff, etc.

On December 8, 2022, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) and the Centers for Disease Control and Prevention (CDC) recommended use of an Omicron (bivalent) **Moderna booster shot** in people ages 6 months through 5 years and recommended use of an Omicron (bivalent) **Pfizer-BioNTech primary series shot** in people ages 6 months through 4 years.

Summary

- **Moderna Omicron (bivalent) vaccines** are authorized as a **booster** for those ages 6 months through 5 years who completed the Moderna 2-dose primary series at least 2 months prior.
- **Pfizer Omicron (bivalent) vaccines** are authorized **only as the third dose in the 3-dose primary series**, with NO BOOSTER for ages 6 months through 4 years.
 - An original (monovalent) Pfizer vaccine is administered as the first and second dose, followed by one Omicron (bivalent) Pfizer vaccine as the third dose in the 3-dose primary series – **administered at least 2 months after the second** (original/monovalent) dose.
- **The Pfizer updated Omicron (bivalent) vaccine is not authorized** as a booster for children ages 6 months through 4 years, including those who completed a Pfizer 3-dose primary series. That is, there is **no Pfizer booster** (monovalent or bivalent) for anyone ages 6 months through 4 years at this time.
- There is **no mix-and-match** for Moderna and Pfizer for any dose of any type in infants and children ages 6 months through 4 years.

Moderna COVID-19 Omicron (Bivalent) Boosters

The **Moderna COVID-19 Omicron (bivalent) booster** is authorized as a single booster dose administered at least 2 months after completion of the 2-dose primary series vaccination with the Moderna original (monovalent) COVID-19 vaccine.

- The Moderna Omicron (bivalent) vaccine for individuals ages 6 months through 5 years is supplied in a multiple-dose vial with a **dark pink cap and a label with a yellow box**.
- Carefully read the labels to differentiate among the Moderna COVID-19 vaccines.

- Note that **each vial contains 2** doses.
- The volume of a single booster dose for ages 6 months through 5 years is **0.2 mL**.

This Moderna product is **not diluted** prior to use (same as other Moderna COVID-19 vaccines).

Pfizer-BioNTech COVID-19 Omicron (Bivalent) Vaccine

The **Pfizer-BioNTech** COVID-19 Omicron (bivalent) vaccine is authorized as the **third dose** of the 3-dose primary series, following two doses of the *monovalent* Pfizer COVID-19 vaccine in children 6 months through 4 years of age.

- Dose 3 of the Pfizer COVID-19 Omicron (bivalent) vaccine is administered at least 8 weeks after dose 2 (doses 1 and 2 are the monovalent vaccine) to complete the 3-dose primary series for ages 6 months through 4 years.
- The Pfizer Omicron (bivalent) vaccine for individuals 6 months through 4 years of age is supplied in multiple dose vials with **maroon caps and labels with maroon borders**.
- The volume after dilution of a single dose for ages 6 months through 4 years is **0.2 mL**.

This Pfizer product **MUST BE DILUTED** before use (as with the monovalent product for this age group, dilute with 2.2 mL sterile 0.9% Sodium Chloride Injection, USP prior to use).

Other Considerations

❖ *Special Situations*

There are important considerations for children who will transition between ages 4 and 5 years during their Pfizer primary series, and between ages 5 and 6 years during their Moderna primary series. There is also expanded information on interchangeability (i.e., no mix-and-match for ages 6 months through 4 years).

Special Situations: <https://bit.ly/C19VaxChildSpecialConsid>

❖ *Storage/Handling*

Moderna EUA Fact Sheet: <https://www.fda.gov/media/163785/download>

Pfizer EUA Fact Sheet: <https://www.fda.gov/media/159312/download>

❖ *Important Naming Note*

There are several terms being used across the country to refer to the updated vaccines. “Bivalent” is a term not easily understood or recognized by the general public. Instead, **“Omicron Booster” and “Updated Booster” are commonly used and better understood by the public**. Providers should note that “bivalent,” “Omicron,” and “updated” boosters are referring to the same products.

The [CDC’s Interim Clinical Considerations](#) for the Use of COVID-19 Vaccines and related resources have been partially updated. As the official clinical guidance resources become more fully updated/available, state resources such as the COVID-19 Vaccination Due Date Calculator, FAQs on vaccinate.wv.gov, and Just-in-Time Trainings will also be updated/provided.

For questions about this advisory, contact the Office of Epidemiology and Prevention Services (OEPS) at 1-800-423-1271, ext. 1 and/or 304-558-5358, ext. 1.