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HEALTH ALERT #206 CDC Expands Omicron COVID-19 Booster to Include Children Ages 5 through 11

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

FROM: Ayne Amjad, MD, MPH, Commissioner and State Health Officer

West Virginia Department of Health and Human Resources, Bureau for Public Health

DATE: October 14, 2022

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 October 12, 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 the COVID-19 Omicron updated boosters (i.e., bivalent boosters) from Pfizer-BioNTech for people ages 5-11 years and from Moderna for people ages 6-11 years and 12-17 years.

Updated COVID-19 boosters add Omicron BA.4 and BA.5 spike protein components to the original COVID-19 vaccine composition. This helps the immune system restore protection that may have waned since previous vaccination by targeting variants that are prevalent and highly transmissible in our communities at this time.

Omicron boosters (bivalent) are now for those ages 5 years and older who have completed the primary series with any authorized/approved COVID-19 vaccine, **and** their most recent original (monovalent) COVID-19 vaccine of any kind was at least 2 months ago.

Original (monovalent) COVID-19 vaccines are no longer authorized for use as booster shots. Only Omicron (bivalent) COVID-19 vaccines can be used as booster shots.

The original (monovalent) COVID-19 vaccines remain the only authorized and recommended COVID-19 vaccines for **primary series** vaccination in ages 6 months and older.

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 primary series vaccination or receipt of the most recent booster dose with any authorized or approved original (monovalent) COVID-19 vaccine.

- For individuals 12 years of age and older, a single Moderna Omicron (bivalent) booster dose is 0.5 mL.
- For individuals 6 years through 11 years of age, a single Moderna Omicron (bivalent) booster dose is 0.25 mL.

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This message was directly distributed by the West Virginia Bureau for Public Health to local health departments and professional associations. Receiving entities are responsible for further disseminating the information as appropriate to the target audience.

Categories of Health Alert messages:

Health Alert: Conveys the highest level of importance. Warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation. May not require immediate action. **Health Update:** Provides updated information regarding an incident or situation. Unlikely to require immediate action.

The Moderna COVID-19 Omicron (bivalent) booster is supplied in a multiple-dose vial with a **dark blue cap** and a label with a gray border. This is the **same product** as is authorized for use in ages 18 years and older.

This product is **not** diluted prior to use (as with other Moderna COVID-19 vaccine products).

Pfizer-BioNTech COVID-19 Omicron (Bivalent) Boosters

The Pfizer-BioNTech COVID-19 Omicron (bivalent) booster is authorized as a single booster dose administered at least 2 months after completion of primary series vaccination or receipt of the most recent booster dose with any authorized or approved original (monovalent) COVID-19 vaccine.

 For individuals 5 years through 11 years of age and older, a single Pfizer Omicron (bivalent) booster dose is 0.2 mL.

The Pfizer COVID-19 Omicron (bivalent) booster for ages 5 through 11 is currently supplied in a multidose vial with an **orange cap and label with an orange border**.

This product **MUST BE DILUTED** with 1.3 mL sterile 0.9% Sodium Chloride Injection, USP prior to use.

Other Considerations

Storage/Handling

Storage/handling and more can be found in the EUAs.

Pfizer EUA: https://www.fda.gov/media/162250/download Moderna EUA: https://www.fda.gov/media/161318/download

Original (Monovalent) COVID-19 Vaccines No Longer Authorized as Boosters

As a reminder, if your entity has been offering **original (monovalent) COVID-19 shots for any individuals/groups ages 5 years and older, <u>stop immediately</u>. However, the original mRNA vaccines (Pfizer and Moderna, monovalent) remain authorized and are the only mRNA products recommended for use at this time as the primary series** in individuals ages 6 months and older.

Important Naming Note

There are several terms being used across national, state, and local networks to refer to the updated boosters. While the clinical considerations from CDC, portions of the vial labels, and portions of the EUA refer to them as "Bivalent," this 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. It is essential for providers to note that "bivalent", "Omicron", and "updated" boosters are referring to the same products.

Clinical Considerations & Updates

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 <u>vaccinate.wv.gov</u>, 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.

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