

# HEALTH ADVISORY # 212 CDC Simplifies Use of Omicron (Bivalent) COVID-19 Vaccines

- TO: West Virginia Healthcare Providers, Hospitals and Other Healthcare Facilities
- FROM: Matthew Christiansen, MD, MPH Commissioner and State Health Officer West Virginia Department of Health and Human Resources, Bureau for Public Health
- DATE: April 21, 2023

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 April 18, 2023, the U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) for the Omicron (bivalent) Pfizer-BioNTech and Moderna COVID-19 vaccines to simplify the vaccination schedule for most individuals. Following the regulatory action, the U.S. Centers for Disease Control and Prevention (CDC) issued updated recommendations to allow more flexibility for people at higher risk who want the option of added protection from additional COVID-19 vaccine doses. The FDA intends to make decisions about future vaccinations after receiving recommendations on the Fall strain composition this Summer.

### Summary of Recommendations

- Individuals 65 years and older who have received a single dose of the Omicron (bivalent) vaccine are now authorized to receive <u>one additional dose</u> of the Omicron (bivalent) vaccine at least 4 months following their previous Omicron (bivalent) dose.
- Individuals ages 6 years and older who are moderately to severely immunocompromised and previously received an Omicron (bivalent) mRNA dose may receive an additional Omicron (bivalent) mRNA dose at least 2 months after the last bivalent dose. Then, healthcare providers can determine the need for additional Omicron (bivalent) mRNA doses as needed at least 2 months apart based on the level of immunocompromise for conditions such as stem cell transplant, CAR-T therapy, B-cell depletion, and others. The immunocompromised patient determination remains a self-attestation and does not require additional documentation.
- <u>Individuals who are unvaccinated</u> may receive a single dose of the Omicron (bivalent) vaccine, rather than multiple doses of the mRNA vaccines.
- <u>Individuals who have previously completed their mRNA vaccine primary series</u> and have not yet received a dose of the Omicron (bivalent) vaccine may receive a single dose of the Omicron (bivalent) vaccine, rather than multiple doses of the mRNA vaccines.
- <u>Children ages 6 months through 4 years</u> who are <u>unvaccinated</u> may receive a two-dose series of the Moderna Omicron (bivalent) vaccine (using the vial with a dark blue cap, label with grey border) OR three-

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dose series of the Pfizer-BioNTech Omicron (bivalent) vaccine (using the vial with a maroon cap and label border).

- <u>Children 5 years of age</u> who are <u>unvaccinated</u> may receive two doses of the Moderna Omicron (bivalent) vaccine (using the vial with a dark blue cap, label with grey border) OR a single dose of the Pfizer-BioNTech Omicron (bivalent) vaccine (using the vial with an orange cap and label border).
- <u>Children ages 6 months through 5 years</u> who have received one, two or three doses of the monovalent mRNA COVID-19 vaccine may receive an Omicron (bivalent) vaccine, but the number of doses they receive will depend on the vaccine and their vaccination history.
- Alternatives to mRNA COVID-19 vaccines remain available for people who cannot or will not receive an mRNA vaccine. CDC's recommendations for use of (monovalent) Novavax or Johnson & Johnson's Janssen COVID-19 vaccines are unchanged.

Current <u>data</u> show many West Virginians 5 years of age and older have antibodies to SARS-CoV-2, the virus that causes COVID-19, either from vaccination or infection, which can serve as a basis for the protection provided by the Omicron (bivalent) vaccines. Serious infection from COVID-19 remains a threat for many West Virginians. Individuals are encouraged to stay up to date with their COVID-19 vaccines to prevent the most severe outcomes, such as hospitalization or death.

Most individuals can be up to date on their COVID-19 vaccination by having a single dose of the Omicron (bivalent) vaccine. At this time, the West Virginia Department of Health and Human Resources, Bureau for Public Health recommends all West Virginians stay up to date with their COVID-19 vaccines by ensuring they have received an Omicron (bivalent) shot.

### Monovalent mRNA Disposal and Reporting

As of April 19, 2023, CDC no longer recommends the use of monovalent mRNA COVID-19 vaccine, as all mRNA COVID-19 vaccination is now with the (Omicron) bivalent formulation. To minimize the risk of administration error, providers should:

- Remove all monovalent mRNA vaccine from storage units immediately, even if they are not expired.
- Once all inventory is fully accounted for, remove monovalent mRNA COVID-19 vaccine from the vaccine inventory in the West Virginia Statewide Immunization Information System (WVSIIS).
- Dispose of all monovalent mRNA COVID-19 vaccine vials in accordance with local, state, and federal regulations.
- Report all disposed inventory as wastage.

### **Other Considerations**

- "Bivalent" is a term not easily understood or recognized by the general public. Instead, "Omicron Vaccine" and "Updated Vaccine" are commonly used and better understood. Providers should note that "bivalent," "Omicron," are referring to the same products. Consider using more common language (i.e., Omicron, updated) when discussing options with patients.
- The <u>CDC's Interim Clinical Considerations</u> for the Use of COVID-19 Vaccines and related resources will be updated in the near future. As more official clinical guidance resources become available, state

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resources such as the WV COVID-19 Vaccination Due Date Calculator and FAQs on vaccinate.wv.gov and the WV COVID-19 Messaging Kit will also be updated/provided.

#### <u>Resources</u>

- FDA Press Release: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-• update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines.
- CDC Press Release: https://www.cdc.gov/media/releases/2023/s0419-covid-vaccines.html •

For questions about this health alert, contact the Office of Epidemiology and Prevention Services, Division of Infectious Disease Epidemiology (DIDE) at (304) 558-5358 ext. 2.

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