NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

**NC State Health Director's Statewide Standing Order**
**For**
**Pfizer BioNTech COVID-19, Bivalent (Original and Omicron BA.4/ BA.5 B) Vaccine Administration (single-dose or multi-dose vial) in Patients Ages 12 Years and Older**
**September 2, 2022, Revised November 16, 2022**

**Purpose:** To meet the goal of administering FDA-authorized Pfizer- BioNTech COVID -19, Bivalent Original and Omicron BA.4/BA.5 vaccine, herein known as Pfizer- BioNTech COVID-19 Vaccine, Bivalent, and to protect and save lives in the COVID-19 pandemic by providing BOOSTER vaccines to persons aged 12 years and older who meet the criteria set-forth by the Food and Drug Administration/CDC/ACIP.

NOTE: On September 1, 2022 CDC recommended the use of Pfizer- BioNTech COVID-19 Vaccine, Bivalent as authorized under Emergency Use Authorization by the FDA on August 31, 2022.

**Policy:** This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-74, Sec. 9G.7 or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Booster Vaccines authorized by the FDA per conditions of this order.

NOTE: On October 12, 2022, the FDA authorized use of a single- dose vial of Pfizer- BioNTech COVID-19 Vaccine, Bivalent. The multi-dose vial is still available. The vaccine formulation is the same for both products.

| **COVID-19 Vaccination** | |
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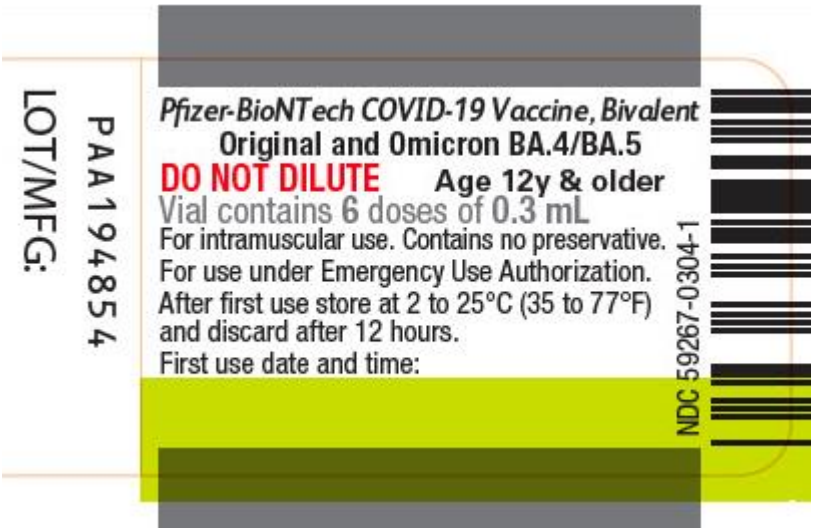
| **Condition/Situation :** | ALERT: Pfizer- BioNTech **multi-dose** COVID-19 Vaccine, Bivalent vaccine has a gray capped vial identical to the primary series COMIRNATY/Pfizer formulation for ages 12 & up. The only distinguishing factor is the vial label states "Bivalent Original and Omicron BA.4/BA.5/Vial contains 6 doses"<br>  <br>Pfizer- BioNTech **single-dose** COVID-19 Vaccine, Bivalent vaccine has a gray capped vial identical to the primary series COMIRNATY/Pfizer formulation for ages 12 & up. The |

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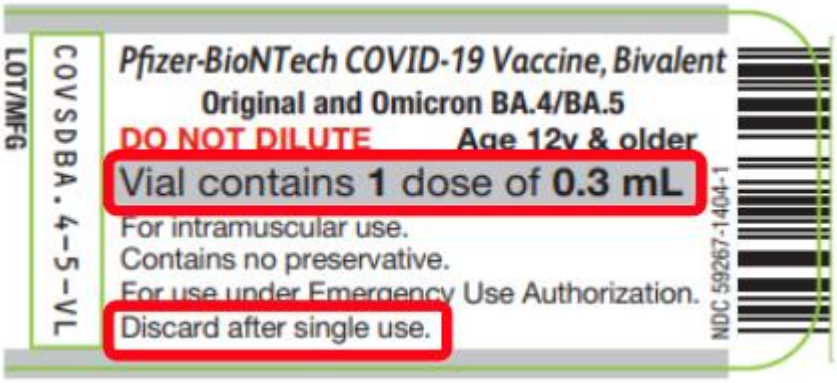
| | distinguishing factors are vial size and label states "Bivalent Original and Omicron BA.4/BA.5"/ **Vial contains 1 dose.**<br><br>  <br><br><br>Patients who have completed a primary series of any COVID 19 vaccination shall receive:<br>One dose of Pfizer- BioNTech COVID-19 Vaccine, Bivalent **if** the<br>• Interval between last dose of primary series of any previously authorized or approved COVID-19 vaccine and Pfizer BioNTech Vaccine, Bivalent has been at least 2 months **or**<br>• Interval between last booster dose of any previously authorized or approved COVID-19 booster vaccine and Pfizer- BioNTech COVID-19 Vaccine, Bivalent has been at least 2 months. |
| **Condition** | In addition to criteria above, the following conditions regarding consent must be met:<br>• Persons 18 years and older, may give effective consent to receive the appropriate dose of Pfizer BioNTech COVID-19 Vaccine, Bivalent for prevention of COVID-19 disease.<br>• Persons 12 – 17 years of age presenting for Pfizer- BioNTech COVID-19 Vaccine, Bivalent presenting for a booster, and whose parent or legal guardian has provided **written** consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status**.** |
| **Assessment Criteria** | |
| **Assessment Criteria** | Patients shall be vaccinated with Pfizer- BioNTech COVID-19 Vaccine, Bivalent based on:<br>1. The conditions/situations of this order (see above).<br>2. Ensure the minimum interval between last primary dose or last booster dose has been met for the dose patient is to receive. |

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| Plan of Care | |
|---|---|
| **Actions** | **Patient Education and Data Collection**<br>Prior to patients receiving Pfizer- BioNTech COVID-19 Vaccine, Bivalent, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include:<br>1. Review CDC Pre-Vaccination Checklist for COVID-19 Vaccine.<br>2. Fact Sheet for Recipients and Caregivers about FDA-authorized Pfizer BioNTech COVID -19 Bivalent Original and Omicron BA.4/BA.5 for 12 Years of Age and Older. Patient should consult primary care or other health care provider if they have questions regarding which bivalent COVID-19 booster vaccine they should receive.<br>3. V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe. |
| | **Pfizer- BioNTech COVID-19 Vaccine, Bivalent Vaccination Administration Procedures**<br>1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States for Pfizer Monovalent COVID-19 vaccine authorized for persons 12 years and older. The administration procedures are the same for the Bivalent booster.<br>2. Pfizer BioNTech Bivalent is supplied in a **GRAY CAP** formulation. The vaccinator shall be familiar with procedures for preparation, storage & handling of the Pfizer BioNTech Bivalent. Dosage and clinical indications are the same for all formulations.<br>a. Review the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for Pfizer BioNTech COVID -19 Bivalent Original and Omicron BA.4/BA.5 for 12 Years of Age and Older (GRAY CAP)<br>3. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA bivalent COVID-19 booster vaccine.<br>4. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order the mRNA bivalent COVID-19 booster vaccine by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with contraindications or precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility. |

5. Review *Special Circumstances*, *Precautions*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the Pfizer- BioNTech COVID-19 Vaccine, Bivalent vaccine.
6. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*, instruct patients accordingly or consult with overseeing provider.
7. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per CDC guidelines for COVID-19 vaccinations to protect against the transmission of COVID-19.

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**Vaccine Product & Preparation**:

8. **Vaccine product:** Pfizer- BioNTech COVID-19 Vaccine, Bivalent vaccine for ages 12 and up is available in single-dose and multi-dose vials. The formulation is the same
    a. A **GRAY CAP** and **Gray Border** on label. Look for "Bivalent" in the label. This vaccine should **NOT** be diluted before use. Label language and vial size are the only distinguishing feature between these products and the COMIRNATY/Pfizer primary series vaccine.
    b. Formulation is 30 mcg/0.3ml.
9. **Preparation**: Prepare vaccine, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling prepared vaccine.
    Pfizer BioNTech COVID-19 Bivalent Original and Omicron BA.4/BA.5 vaccine Preparation and Administration Summary for 12 & Up (GRAY CAP)
10. **Dosing:**
    a. Administer 0.3 mL (30 µg) Pfizer- BioNTech COVID-19 Vaccine, Bivalent vaccine to patients aged 12 and up when withdrawing from a single or multi-dose vial.
    b. When a patient inadvertently receives an incorrect/ inappropriate dose of COVID-19 vaccine, review Interim Clinical Considerations, Appendix D for COVID-19 vaccine errors and deviations, and take action as directed.
11. **Timing:**
    a. **Timing (interval) between last dose of a COVID-19 primary series shall be at least 2 months.**
    b. **Timing (interval) between last booster dose of a COVID-19 vaccine shall be at least 2 months.**
    c. This vaccine may be co-administered with other vaccines, i.e., influenza or other vaccines.

d. See Interim Clinical Considerations, Appendix D for information on COVID-19 vaccine errors and administration deviations.

12. **Administration:**
    a. **Route of Administration:** Administer Pfizer- BioNTech COVID-19 Vaccine, Bivalent by intramuscular (IM) injection in the deltoid muscle of the arm to patients 12 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used.
    b. **Needle Gauge**: Changing needles between drawing up vaccine from a vial and injecting it into a patient is not necessary unless the needle has been damaged, contaminated, or if the needle used to draw up the vaccine is not the correct size for the patient based on their reported weight. Patients may self-report their weight for needle selection purposes. See needle sizing chart below:

| **Sex** and Weight of Patient | Needle Gauge | Needle Length | Injection Site* |
|---|---|---|---|
| Female or male fewer than 130 lbs. | 22–25 | 5/8 ** –1" | Deltoid muscle of arm |
| Female or male 130–152 lbs. | 22–25 | 1" | Deltoid muscle of arm |
| Female 152–200 lbs. | 22–25 | 1-11/2" | Deltoid muscle of arm |
| Male 153–260 lbs. | 22–25 | 1-11/2" | Deltoid muscle of arm |
| Female 200+ lbs. | 22–25 | 11/2" | Deltoid muscle of arm |
| Male 260+ lbs. | 22–25 | 11/2" | Deltoid muscle of arm |

* Alternatively, the anterolateral thigh also can be used.

** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

13. **Multiple vaccinations:** If multiple vaccines are administered at a single visit, administer each injection in a different injection site following guidance in the CDC Interim Clinical Considerations.
14. **Bleeding Risk**: Patients with blood disorders or who are on blood thinners: administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes.
15. **Documentation:**
    a. **CVMS/NCIR**: Document vaccine record in CVMS or NCIR **within 24 hours** after vaccine administration per system guidelines found at: https://immunize.nc.gov/providers/covid-19training.htm. If vaccine is documented in the EHR within 24 hours, providers have **no more than 72 hours** from administration to also enter data in CVMS or NCIR.

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| | Determining whether to document in CVMS versus NCIR should occur according to site protocol; it is not necessary to document in both systems.<br>b. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 booster vaccination in agency electronic medical record per agency policy.<br>c. Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacturer, lot number, date of vaccination, name/location of vaccinator and clinic site. |
| | **Pfizer- BioNTech COVID-19 Vaccine, Bivalent Vaccination Observation and Follow-Up**<br><br>1. **Post-vaccination Observation**: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines for the following time periods:<br>a. **30 minutes:**<br>• Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine<br>• Persons with a history of anaphylaxis due to any cause<br>• People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to a viral vector vaccine-Janssen/Johnson and Johnson who receive a mRNA vaccine-COMIRNATY or Moderna/SPIKEVAX)<br>• Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy<br>b. **15 minutes:** All other persons<br>2. **Anaphylaxis Management**: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis.<br>3. **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting. |
| **Special Circumstances** | **People who received COVID-19 vaccination outside the United States:** The recommendations for people vaccinated outside of the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Refer to Interim Clinical Considerations, Appendix B |

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| | (People who received COVID-19 vaccine outside the United States) and take action/ consult with medical provider as directed.<br><br>**Participants in clinical trials within or outside the United States (see** Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix C) who received all the recommended primary series doses of a WHO-EUL COVID-19 vaccine (i.e., not placebo) that is not FDA-approved or FDA-authorized are considered fully vaccinated. In addition, individuals who received a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy are considered fully vaccinated. *These persons require medical consultation.<br>If clinical trial participants have questions about whether they should receive a booster dose outside of the clinical trial, they should consult with their healthcare provider. Clinical trial participants who did not receive all the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-authorized COVID-19 bivalent booster vaccine. |
| **Follow-up** | Adverse events that occur in a recipient following any COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:<br>1. Vaccine administration errors<br>2. Serious adverse events<br>3. Cases of Multisystem Inflammatory Syndrome<br>4. Cases of COVID-19 that result in hospitalization or death<br>Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.govexternal icon or by calling 1-800-822-7967. |
| **Precautions for Use of this Order** | 1. Persons with a history of an immediate allergic reaction to any other vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]). This includes people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, even if it is unknown which component elicited the immediate allergic reaction.<br>2. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to another (e.g., mRNA – COMIRNATY/Pfizer or Moderna/SPIKEVAX) because of potential cross-reactive hypersensitivity. Consultation with an allergist-immunologist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under the supervision of a health care provider experienced in the management of severe allergic reactions.<br>3. Patient self-reported moderate to severe acute illness. |

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| | 4. Persons with a history of myocarditis or pericarditis.<br>5. Persons with a history of MIS-C or MIS-A.<br>6. Persons with a precaution to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination |
| **Contraindications for Use of this Order** | Do not administer the **Pfizer- BioNTech COVID-19 Vaccine, Bivalent** vaccine to individuals with a history of:<br>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine<br>• Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.<br>See Interim Clinical Considerations, Appendix E: Triage of people with history of allergies or allergic reactions |
| **Criteria or Circumstances for Notifying Medical Provider** | 1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service.<br>2. Patient reports a precaution for the vaccine.<br>3. COVID-19 vaccine history cannot be determined or is not available.<br>4. Patients vaccinated with COVID-19 vaccines not authorized or approved in the US.<br>5. Patients vaccinated with active COVID-19 vaccine as part of a clinical trial.<br>6. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred.<br>7. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order.<br>Note: Healthcare providers or health departments in the United States can request a consultation from CISA COVID vax for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines. |

Approved by: _ CTilson

Date Signed: 11-16-22

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

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