NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for Pfizer-BioNTech mRNA COVID-19 Bivalent (Original and Omicron BA.4/ BA.5 B) **Booster Vaccine Administration in Patients Ages 5-11 Years**
October 12, 2022

Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and to administer Pfizer-BioNTech (herein-after Pfizer vaccines) to persons who meet criteria set-forth by the Food and Drug Administration in accordance with FDA Emergency Use Authorization.

Note: On 10/12/22, CDC recommended that all children ages 5-11 who had completed their primary series of monovalent Pfizer-BioNTech vaccine receive an authorized bivalent booster vaccine. The time interval between the last vaccine in the primary series or the last monovalent booster and the bivalent booster vaccine should be at least 2 months. The use of monovalent vaccines as booster doses was rescinded.

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 2022-72, Sec. 9G.7.(a)-(e) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.

COVID-19 Vaccination	
Condition or Situation	Patients 5-11 years old who have completed a primary series, presenting for Pfizer COVID-19 Bivalent booster vaccination authorized by the FDA through an Emergency Use Authorization (EUA). Parent or legal guardian of the patient (recipient of vaccine) must provide **written consent** prior to the patient being vaccinated with Pfizer COVID-19 vaccine, per Session Law 2021 SECTION 9. G. S. 90 21.5
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Pfizer- BioNTech COVID-19 Vaccine, Bivalent 5-11years old based on: 1. The conditions/situations of this order (see above). **2. Patients (5-11 years old) have completed the recommended primary series based on their immune status of either authorized or approved monovalent COVID-19 vaccine and it has been at least 2 months since their last primary dose or monovalent booster.**
Plan of Care	
	Patient Education and Data Collection Prior to patients receiving the COVID-19 vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient and parent/ legal guardian, which at a minimum shall include: 1. CDC Pre-Vaccination Checklist for COVID-19 Vaccine 2. Fact Sheet for Recipients and Caregivers About the Pfizer COVID-19 Vaccine for Use in Individuals 5-11 Years of Age 3. V-safe information sheet to vaccine recipients and their parent/legal guardian and encourage vaccine recipients to participate in V-safe.

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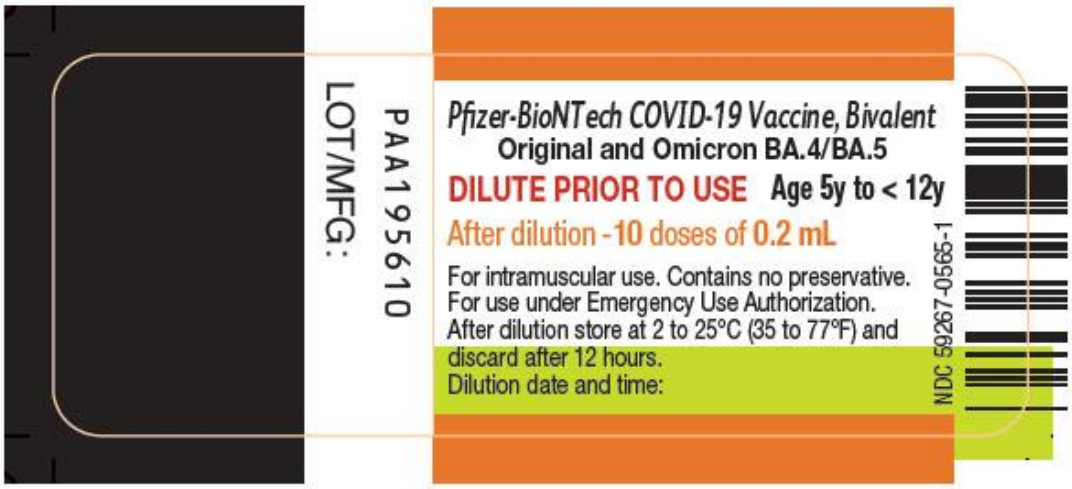
Pfizer COVID-19 Vaccination Administration Procedures

1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.
2. Review the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for Pfizer Bivalent Booster Vaccine for 5-11 Years of Age. This is a new Pfizer-BioNTech product.
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 a bivalent COVID
4. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines 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 COVID-19 vaccine.
6. Following the current *CDC Pre-vaccination Checklist for COVID-19 Vaccines and CDC Pre-vaccination Checklist for COVID-19 Vaccines Information for HCPs*, instruct patients accordingly or consult with overseeing provider.
    a. The pre-vaccination checklist shall be followed with the following exception: COVID-19 vaccination should ***not*** be deferred in patients who received treatment with convalescent plasma.
7. Written consent must be obtained from the patient's parent or legal guardian prior to vaccine administration per agency policy and in accordance with NC General Statute. 90-21.13 and NC General Statute 90-21.5 and Session Law 2021-110.
8. 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.

Vaccine Product & Preparation:

1. **Vaccine product:** ensure the appropriate Pfizer formulation is selected. Pfizer COVID-19 Bivalent vaccine for use as booster in ages 5-11 (10 µg) has an **ORANGE** cap and label and is marked "Bivalent Age 5y to <12y". This is the only distinguishing feature between the monovalent ORANGE cap product and the bivalent product.



2. Preparation: Mix, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling and mixing vaccine.

3. Dosing:

a. Administer 0.2mL (10 µg) Pfizer COVID-19 Bivalent booster vaccine to patients aged 5-11.

b. Inadvertent administration of an incorrect/inappropriate dose or formulation of COVID-19 vaccine review Interim Clinical Considerations, Appendix D COVID-19 vaccine errors and deviations and take action as directed.

4. Timing:

a. Booster doses shall be administered at least 2 months after the last dose of the primary series or 2 months after most recent booster dose.
b. See Interim Clinical Considerations, Appendix D for information on COVID-19 vaccine errors and administration deviations.

5. Administration:

a. Route of Administration: Administer Pfizer vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 5-11 years of age. The deltoid muscle is the preferred IM injection site for this age group. 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 age. See needle sizing chart below:

Age of Patient	Needle Gauge	Needle Length	Injection Site
5-10 years old	16-25 mm	*5/8-1 inch	Deltoid muscle
	25-32 mm	1-1.25 inches	Anterolateral thigh
11 years old	16-25 mm	*5/8-1 inch	Deltoid muscle
	25-38 mm	1-1.25 inches	Anterolateral thigh

* A 5/8-inch needle may be used in patients weighing less than 130lbs in the deltoid only if subcutaneous tissues are not bunched and injection is made at 90-degree angle.

a. **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. Injection sites should be separated by at least 1 inch.
   i. In patients who are 11 years old, the deltoid muscle can be used.
   ii. In patients who are 5-10 years old, if more than 2 vaccines are injected in the same limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site due to greater muscle mass.

6. 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. Determining whether to document in CVMS versus NCIR should occur according to site protocol; it is not necessary to document in both systems.

b. Electronic Medical Record: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.

c. Provide vaccine recipients and their parent/ legal guardian with 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 COVID-19 Vaccination Observation and Follow-Up

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:
   a. **30 minutes:**

	i. Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine ii. Persons with a history of anaphylaxis due to any cause iii. 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/Pfizer or Moderna/SPIKEVAX) should be observed for 30 minutes following vaccination. iv. Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy b. **15 minutes**: All other persons 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. 3. **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly 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 (People who received COVID-19 vaccine outside the United States) and take action/ consult with medical provider as directed. **Participants in clinical trials within or outside the United States** 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. They are also eligible for a booster dose Pfizer-BioNTech COVID-19 Vaccine at least 5 months after completing the Pfizer 2 dose primary series for immune competent children. Those who are moderately to severely immunocompromised should wait at least 3 months after their third primary series dose. 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. Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC Appendix C

	• Moderately or severely immunocompromised clinical trial participants should receive an additional dose of Pfizer-BioNTech COVID-19 Vaccine after receiving their 2nd dose of a primary series. • Clinical trial participants (including moderately or severely immunocompromised people who received a 3-dose primary series) **should** receive a single booster dose of Pfizer-BioNTech COVID-19 Vaccine 3 months after completing the third primary series dose. If clinical trial participants have questions about whether they should receive an additional and/or 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-approved or FDA-authorized COVID-19 vaccine series.
Follow-up	Adverse events that occur in a recipient following 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: • Vaccine administration errors Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix D. Administration errors should be reported to VAERS • Serious adverse events • Cases of Multisystem Inflammatory Syndrome • Cases of COVID-19 that result in hospitalization or death 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.gov 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. 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. 3. Patient or parent/legal guardian on their behalf reports moderate to severe acute illness.

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	4. Patient or parent/legal guardian on their behalf who report 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. 5. Persons with a history of myocarditis or pericarditis. 6. Persons with a history of MIS-C.
Contraindications for Use of this Order	Do not administer the COVID-19 Vaccine to individuals with a history of: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine • Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.
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. 2. Patient or parent/legal guardian on their behalf reports a precaution for the vaccine. 3. COVID-19 vaccine history cannot be determined or is not available. 4. Patients vaccinated with COVID-19 vaccines not authorized or approved in the US. 5. Patients vaccinated with active COVID-19 vaccine as part of a clinical trial. 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. 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. Note: Healthcare providers or health departments in the United States can request a consultation from CISA COVIDvax 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: ___ ___ Date Signed: _10-12-2022_____
Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

This standing order is effective immediately and authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-72, Sec. 9G.7.(a)-(e) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.