



**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 The use of monovalent vaccines as booster doses was rescinded.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 2022-74, 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	<p>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).</p> <p>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</p>
Assessment Criteria	
Assessment Criteria	<p>Patients shall be vaccinated with Pfizer- BioNTech COVID-19 Vaccine, Bivalent 5-11years old based on:</p> <ol style="list-style-type: none"> The conditions/situations of this order (see above). <u>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.</u>
Plan of Care	
Patient Education and Data Collection	<p>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:</p> <ol style="list-style-type: none"> CDC Pre-Vaccination Checklist for COVID-19 Vaccine Fact Sheet for Recipients and Caregivers About the Pfizer COVID-19 Vaccine for Use in Individuals 5-11 Years of Age V-safe information sheet to vaccine recipients and their parent/legal guardian and encourage vaccine recipients to participate in V-safe.



**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**

Pfizer COVID-19 Vaccination Administration Procedures

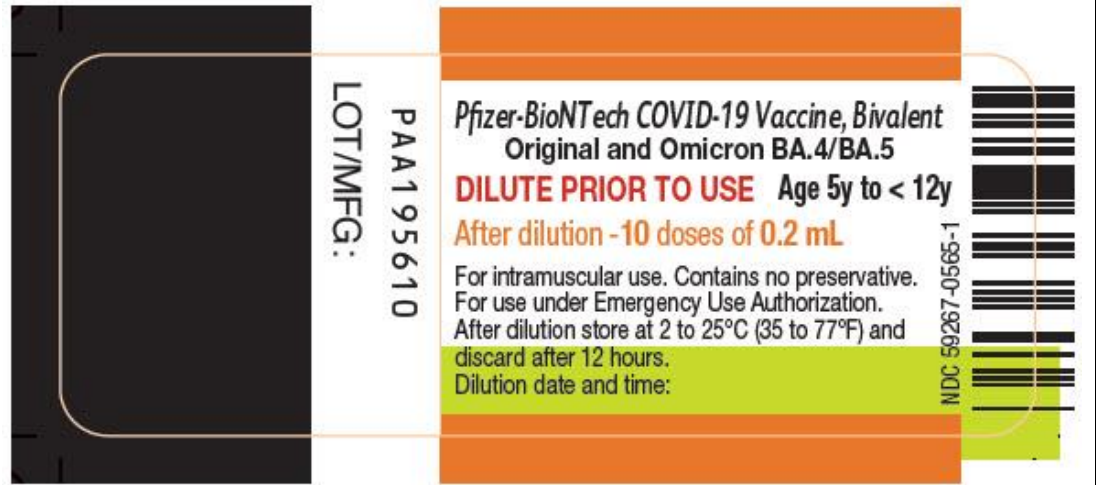
1. Review [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#).
2. Review the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for [Pfizer Bivalent Booster Vaccine for 5-11 Years of Age](#). This is a 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.



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



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:



**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**

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:**



**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**

	<ul style="list-style-type: none">i. Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccineii. Persons with a history of anaphylaxis due to any causeiii. 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 <p>b. 15 minutes: All other persons</p> <p>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.</p> <p>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.</p>
Special Circumstances	<p>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.</p> <p>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</p>



**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**

	<ul style="list-style-type: none"> 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.
<p>Follow-up</p>	<p>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:</p> <ul style="list-style-type: none"> Vaccine administration errors <p>Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in <u>Appendix D</u>. Administration errors should be reported to <u>VAERS</u></p> <ul style="list-style-type: none"> Serious adverse events Cases of Multisystem Inflammatory Syndrome Cases of COVID-19 that result in hospitalization or death <p>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.</p>
<p>Precautions for Use of this Order</p>	<ol style="list-style-type: none"> 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. 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. Patient or parent/legal guardian on their behalf reports moderate to severe acute illness.



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

Table with 2 columns: Criteria/Section and Details. Rows include: 4-6. Patient or parent/legal guardian...; Contraindications for Use of this Order; Criteria or Circumstances for Notifying Medical Provider.

Handwritten signature: E. Cuervo Tilson

Approved by: Elizabeth Cuervo Tilson, MD, MPH NPI: 1760540421

Date Signed: 10-12-2022

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 2022-74, 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.