



**NC State Health Director’s Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6
months through 4 Years
December 9, 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](#).

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.

Note: On December 8, 2022, the FDA authorized the use of a **new** Pfizer BioNTech COVID-19 bivalent vaccine for children ages 6 months through 4 years with CDC recommendation on 12/9/22. This **new** product will be referred to as “Pfizer-BioNTech COVID-19 Vaccine, Bivalent” throughout the entirety of this standing order. The new bivalent product will be administered as the 3rd does in the primary series instead of the monovalent product. Additionally, authorization of Pfizer BioNTech COVID-19 Monovalent Vaccine as a third dose in the primary series was withdrawn.

COVID-19 Vaccination

Condition/ Situation:

ALERT: This standing order covers the use of 2 different Pfizer- BioNTech products for the completion of the primary series in children ages 6 months through 4 years of age. To determine previous vaccination status consult NCIR/CVMS, child’s vaccination card, or accept parental attestation. All COVID-19 vaccines for this age group were mRNA monovalent vaccines prior to 12/8/22. No mixing between Pfizer and Moderna products is allowed in this age group. Children who received all 3 doses of Pfizer monovalent and have not yet had their 5th birthday are not eligible for a booster of any type.

Patients present requesting vaccination will receive, with appropriate written consent from an authorized caregiver:

- **Pfizer COVID-19 Monovalent Vaccine 6 months through 4 years Primary Series (1st or 2nd doses):**
 - 6 months through 4 years of age presenting for a 3-dose primary series vaccination with written consent from an authorized caregiver (see consent requirements below). Dose 2 shall be given at least 21 days after Dose 1.
- **Pfizer-BioNTech COVID-19 Vaccine, Bivalent (new product) 6 months through 4 years** shall be given at least 8 weeks after Dose 2 and considered as the 3rd dose of the 3 dose primary vaccination series. See [Table 2](#) vaccination schedule in CDC Interim Clinical Considerations.



**NC State Health Director’s Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6
months through 4 Years
December 9, 2022**

| | | | | | | | | | |
|---|--|--|--|------------------|--------------|---|--|------------------|-------------------------|
| | <p>Table 1</p> <table border="1"> <tr> <td colspan="2">Dose Intervals for Pfizer COVID-19 Monovalent Vaccine Primary Series for 6 months through 4 years:</td> </tr> <tr> <td>Dose 1 to Dose 2</td> <td>3 – 8 weeks*</td> </tr> </table> <p>Table 2</p> <table border="1"> <tr> <td colspan="2">Dose Intervals for Pfizer-BioNTech COVID-19 Vaccine, Bivalent (for completion of Primary Series) 6 months through 4 years-Primary Series:</td> </tr> <tr> <td>Dose 2 to Dose 3</td> <td>At least 8 weeks</td> </tr> </table> <p>*If patient has only received 1 dose of monovalent vaccine, they must receive a 2nd dose of monovalent before receiving the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to complete the primary series.</p> <p>*See “Patient Education and Data Collection” and considerations for intervals for mRNA COVID-19 vaccine primary series for information on counselling patients on the interval between dose 1 and dose 2. See Table 2 vaccination schedule in CDC Interim Clinical Considerations.</p> | Dose Intervals for Pfizer COVID-19 Monovalent Vaccine Primary Series for 6 months through 4 years: | | Dose 1 to Dose 2 | 3 – 8 weeks* | Dose Intervals for Pfizer-BioNTech COVID-19 Vaccine, Bivalent (for completion of Primary Series) 6 months through 4 years-Primary Series: | | Dose 2 to Dose 3 | At least 8 weeks |
| Dose Intervals for Pfizer COVID-19 Monovalent Vaccine Primary Series for 6 months through 4 years: | | | | | | | | | |
| Dose 1 to Dose 2 | 3 – 8 weeks* | | | | | | | | |
| Dose Intervals for Pfizer-BioNTech COVID-19 Vaccine, Bivalent (for completion of Primary Series) 6 months through 4 years-Primary Series: | | | | | | | | | |
| Dose 2 to Dose 3 | At least 8 weeks | | | | | | | | |
| Assessment Criteria | | | | | | | | | |
| Assessment Criteria | <p>Patients 6 months through 4 years of age shall be vaccinated with Pfizer COVID-19 Vaccine based on:</p> <ol style="list-style-type: none"> 1. The conditions/situations of this order (see above). 2. The patient is presenting for first dose of Pfizer and there is no history of previous COVID-19 vaccination, regardless of brand. 3. The patient is presenting for a primary series dose of Pfizer and the minimum interval between doses has been met (for further guidance see CDC Clinical Considerations COVID-19 vaccination schedule) 4. Availability of maroon cap under 5 vaccine, both monovalent and bivalent formulations. | | | | | | | | |
| Plan of Care | | | | | | | | | |
| Actions | <p>Patient Education and Data Collection</p> <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, which at a minimum shall include:</p> <ol style="list-style-type: none"> 1. Review CDC Pre-Vaccination Checklist for COVID-19 Vaccine. 2. Fact Sheet for Recipients and Caregivers About Pfizer-BioNTech COVID-19 Vaccine for 6 Months through 4 Years of Age. Patient’s authorized caregiver should consult primary care or other health care provider if they have questions | | | | | | | | |



NC State Health Director’s Statewide Standing Order for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6 months through 4 Years December 9, 2022

regarding which COVID-19 vaccine they should receive. Refer to [Interim Clinical Considerations](#) for latest vaccine information.

- 3. [V-safe information](#) sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.

Pfizer COVID-19 Vaccine 6 months through 4 years:

Administration Procedures

- 1. Review [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#).
- 2. Pfizer COVID-19 vaccine for pediatric patients 6 months through 4 years of age is supplied in a **MAROON CAP** formulation. No other formulation should be used in this population. The vaccinator shall be familiar with procedures for preparation, storage & handling of the Pfizer formulation they are using.
a. Review the [Fact Sheet for Healthcare Providers Administering Pfizer Vaccine for 6 Months Through 4 Years \(MAROON CAP ONLY\)](#)
- 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 COVID-19 vaccine.
- 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. More information is available at this site - CDC [COVID-19 Vaccines for Special Populations](#).
- 6. Following the current [CDC Pre-Vaccination Checklist for COVID-19 Vaccines](#), 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 monoclonal antibody treatment or convalescent plasma.
- 7. When vaccinating a minor with **Pfizer COVID-19 vaccine**, consent must be obtained from the patient’s authorized caregiver prior to administration per conditions of this order, agency policy and in accordance with [NC General Statute 90-21.13](#) and [Minor Consent Law](#) and [Session Law 2021-110. \(Section 9, a1\)](#)



**NC State Health Director's Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6
months through 4 Years
December 9, 2022**

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. In general, the same mRNA vaccine product should be used for all doses in the primary series. See [CDC guidance for exceptional situations](#)
 - a. The Pfizer monovalent formulation for ages 6 months through 4 years has a **MAROON CAP** and label. PLEASE NOTE: Vial labels and carton labels may state "Age 2y to < 5y" or "Age 6m to < 5y". Vials with either printed age range CAN be used for individuals 6 months through 4 years of age. This vaccine **must be diluted** before use. Use of any other formulation in this age group will result in administration error.
 - b. The Pfizer bivalent formulation for ages 6 months through 4 years also has a **MAROON CAP** and label. The only difference between the monovalent and bivalent vaccine is the wording on the label, "Bivalent (Original and Omicron BA.4/BA.5). This vaccine must be diluted prior to use. Discard 12 hours after first puncture.
2. **Preparation:** Prepare vaccine, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling prepared vaccine. When using the **MAROON CAP** formulation, refer to [Pfizer COVID-19 Vaccine Fact Sheet for Health Care Providers Dose Preparation for 6 months through 4 years formulation \(MAROON CAP\)](#) Once vial is punctured it must be discarded after 12 hours.
3. **Dosing:**
 - a. Administer 0.2 mL (3 µg) Pfizer COVID-19 monovalent or bivalent vaccine to patients 6 months through 4 years of age based on dose sequence **Diluent is required.**
 - b. Patients shall receive the same brand of COVID-19 vaccine for their entire primary series. If a dose of a different mRNA product is inadvertently administered, that dose is valid and does not need to be repeated. For further information see guidance on vaccine administration errors and deviations ([CDC Interim Clinical Considerations for COVID-19 Vaccine Administration Appendix D](#)).
 - c. When a patient inadvertently receives an incorrect/inappropriate dose of COVID-19 vaccine, review [Appendix D. Vaccine administration errors and deviations](#), and take action as directed.



**NC State Health Director’s Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6
months through 4 Years
December 9, 2022**

9. Timing:

- a. All recommended doses of Pfizer shall be administered as close to the recommended interval as possible. Doses that are given up to 4 days (the “grace period”) before the recommended interval are valid and should not be repeated. The 4-day grace period shall not be used to prospectively schedule or administer a COVID-19 vaccine dose earlier than recommended. (See interval tables above)
- b. People should receive the recommended age-appropriate vaccine dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), the vaccinator should check the CDC Interim Clinical Considerations on [Transitioning from a younger to older age group](#).

10. Administration:

- a. **Route of Administration:** Use the chart below to determine appropriate needle gauge and site of intramuscular injection.

| Age of Patient | Needle Gauge | Needle Length | Injection Site |
|----------------------|--------------|------------------|---------------------|
| Infants, 6-12 months | 25 mm | 1 inch | Anterolateral thigh |
| Toddlers, 1-2 years | 25-32 mm | 1-1.25 inch | Anterolateral thigh |
| | 16-25 mm | *5/8 inch-1 inch | Deltoid muscle |
| Children, 3-5 years | 16-25 mm | *5/8 inch-1 inch | Deltoid muscle |
| | 25-32 mm | 1-1.25 inch | Anterolateral thigh |

- 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. Patient’s authorized caregiver may self-report the child’s weight for needle selection purposes. *If a 5/8-inch needle is used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

11. Multiple vaccinations: If multiple vaccines are administered at a single visit, administer each injection in a different injection site following guidance in the [CDC](#)



**NC State Health Director's Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6
months through 4 Years
December 9, 2022**

[Interim Clinical Considerations - COVID-19 vaccine and coadministration with other vaccines.](#)

12. **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.
13. **Documentation:**
 - a. Patient or caregiver attestation to severe or moderate immunocompromise should be done within the notes section in CVMS or comparable section of an EHR or other documenting systems.
 - b. **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.
 - c. **Electronic Medical Record:** If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.
 - d. 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.
 - e. Counsel when and how patient needs to schedule return appointment for second, third, or booster dose of COVID-19 vaccine, if applicable.

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:**
 - Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine
 - Persons with a history of anaphylaxis due to any cause
 - 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-Pfizer or Moderna/SPIKEVAX) should be observed for 30 minutes following vaccination.



**NC State Health Director's Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6
months through 4 Years
December 9, 2022**

| | |
|------------------------------|---|
| | <ul style="list-style-type: none">• 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> <ol style="list-style-type: none">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 | <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 A (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. 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. For more information go to Appendix B. People who received COVID-19 vaccine as part of a clinical trial</p> <ol style="list-style-type: none">1. Moderately or severely immunocompromised clinical trial participants should receive an additional dose of Pfizer-BioNTech COVID-19 Vaccine 28 days after receiving the second vaccine dose of a primary series as detailed above, unless they have received or plan to receive an additional or booster dose through a clinical trial.2. 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. |



**NC State Health Director’s Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6
months through 4 Years
December 9, 2022**

| | |
|---|--|
| <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> <ol style="list-style-type: none"> 1. Vaccine administration errors 2. Serious adverse events 3. Cases of Multisystem Inflammatory Syndrome 4. 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.govexternal icon or by calling 1-800-822-7967.</p> |
| <p>Precautions for Use of this Order</p> | <ol style="list-style-type: none"> 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 self-reported moderate to severe acute illness. 4. 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. 5. Persons with a history of myocarditis or pericarditis. 6. Persons with a history of MIS-C or MIS-A. |
| <p>Contraindications for Use of this Order</p> | <p>Do not administer the COVID-19 Vaccine to individuals with a history of:</p> <ul style="list-style-type: none"> • 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. <p>See additional guidance: Interim Clinical Considerations, Appendix E: Triage of people with history of allergies or allergic reactions</p> |



NC State Health Director’s Statewide Standing Order for Administering Pfizer-BioNTech Covid-19 Monovalent and Bivalent Vaccine as a primary series in Children 6 months through 4 Years December 9, 2022

Table with 2 columns: Criteria or Circumstances for Notifying Medical Provider and a list of 7 conditions for vaccination. Includes a note about healthcare providers and CISA COVID vax.

Approved by: [Signature] Elizabeth Cuervo Tilson NPI: 1760540421

Date Signed: 12/13/2022

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.