



COMPANION DOCUMENT

**NC State Health Director’s Statewide Standing Order
for COMIRNATY/Pfizer mRNA COVID-19 Vaccine Administration in Patients Age 12 Years and Older
Revised January 7, 2022**

Purpose: To meet the goal of administering [FDA-approved \(COMIRNATY\)](#), [FDA-Emergency Use Authorization \(Pfizer BioNTech\)](#) herein-after COMIRNATY/Pfizer vaccines and to protect and save lives in the COVID-19 pandemic by vaccinating persons age 12 years and older who meet the criteria set-forth by the Food and Drug Administration.

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 [Executive Order 245](#), or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively “vaccinators”) to administer FDA approved COVID-19 Vaccines and/or COVID -19 vaccines authorized by the FDA through an Emergency Use Authorization (EUA) per conditions of this order.

COVID-19 Vaccination	
Condition or Situation	<p><u>Primary 2-Dose Series under the following situations:</u></p> <ul style="list-style-type: none"> Patients 12 years and older, presenting for Pfizer/COMIRNATY vaccine for the first or second dose of their 2-dose primary series. <p><u>3rd Dose Primary Series under the following situations:</u></p> <ul style="list-style-type: none"> Patients 12 years and older, who self attest to: <ul style="list-style-type: none"> Being <u>moderately to severely immunocompromised</u>, who present at least 28 days after their second dose of mRNA vaccine and are requesting the third dose of their three-dose primary series of mRNA vaccine. <p>**For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who self-identify as moderately to severely immunocompromised and present requesting an additional dose of COMIRNATY/Pfizer, refer to section on “Special Circumstances.”</p> <p><u>Pfizer/COMIRNATY Booster Dose situations:</u></p> <ul style="list-style-type: none"> <u>Pfizer/COMIRNATY COVID-19 Vaccination primary series:</u> Anyone 12 years of age and older, who present requesting a booster dose at least 5 months after completion of their primary series with Pfizer/COMIRNATY. <u>Moderna COVID-19 Vaccination primary series:</u> Anyone 18 years of age and older, who present requesting a booster dose at least 6 5 months after completion of their primary series with Moderna. <u>Janssen COVID-19 Vaccination primary series:</u> Anyone 18 years and older, who received primary COVID-19 vaccination with Janssen at least 2 months ago. <p>*Regarding booster doses: patients 18 years of age and older can receive any brand of COVID-19 vaccine for their booster shot, upon their request.</p> <p>**For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting booster dose of COMIRNATY/Pfizer, refer to section on “Special Circumstances.”</p>



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Patients will be vaccinated under the following conditions:

- 1. Patients (recipients of vaccine) 16-years of age or older who present requesting COMIRNATY/Pfizer vaccine for the first 2 dose series and have legal and decisional capacity to consent to the vaccine will be vaccinated under FDA approved status per NCAC minor consent law and NC G.S 90-21.13.
2. Patients (recipients of vaccine) 12 – 15 years of age presenting for COMIRNATY/Pfizer for the first 2 dose series, patients (recipients of vaccine) 12 – 17 years of age presenting for COMIRNATY/Pfizer for a 3rd dose in primary series due to immunocompromised conditions, and patients 12-17 years of age presenting for a booster dose of Pfizer/COMIRNATY and whose parent or legal guardian has provided written consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status.
3. Patients 18 years of age or older who present requesting a third dose of a primary series due to immunocompromised conditions or a booster dose based on the criteria above and have legal and decisional capacity to consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status.

NOTE: Patients should receive the age-appropriate formulation of Pfizer based on the age they are the day of vaccination.

Assessment Criteria

Assessment Criteria

Patients shall be vaccinated with COMIRNATY/Pfizer COVID-19 Vaccine based on:

- 1. the conditions of this order
2. If patient is presenting for first dose of Pfizer/COMIRNATY: ensure there is no history of previous COVID-19 vaccination, regardless of brand.
3. If patient is presenting for second, third, or booster dose of COMIRNATY/Pfizer: ensure that the minimum interval between doses has been met. Timing (interval) of booster dose is determined by what brand of COVID-19 Vaccine was administered for Primary Series. See the below charts for minimum intervals between doses:

Intervals for Doses in the Primary Series

Table with 2 columns: Dose description and Interval. Row 1: Dose 1 to Dose 2 of COMIRNATY/Pfizer, 21 days. Row 2: *Dose 2 to Dose 3 of COMIRNATY/Pfizer, 28 days.

*see the section above on third doses to determine if a three-dose primary series is appropriate.



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Intervals for Booster Doses			
Primary Series Vaccine	Age for vaccine booster	Interval between final primary dose and booster dose	COVID-19 product that may be given as a booster dose
Pfizer/COMIRNATY	≥ 18 years	≥ 5 months	Pfizer Moderna Janssen
Pfizer/COMIRNATY	12-17 years	≥ 5 months	This age group only eligible for Pfizer
Moderna	≥ 18 years	≥ 6 5 months	Pfizer Moderna Janssen
Janssen	≥ 18 years	≥ 2 months	Pfizer Moderna Janssen

*Moderately and severely immunocompromised people over the age of 12 who qualify for a third dose of an mRNA primary series may receive a single COVID-19 booster dose (Pfizer/COMIRNATY, Moderna, or Janssen; as appropriate based on age and assessment criteria above). These patients **may receive a total of four COVID-19 vaccine doses.**

Plan of Care

Actions

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, which at a minimum shall include:

1. Where, how, and when to obtain follow-up COVID-19 vaccinations, as appropriate and as outlined above.
2. [CDC Pre-Vaccination Checklist for COVID-19 Vaccine](#)
3. [Fact Sheet for Recipients and Caregivers About COMIRNATY \(Covid-19 Vaccine, mRNA\) and Pfizer-BioNTech COVID-19 Vaccine for 12 Years of Age and Older.](#)
4. Patient should consult primary care or other health care provider if they have questions regarding which COVID-19 vaccine they should receive for a booster dose. Refer to [Interim Clinical Considerations](#) for latest vaccine information.
5. [V-safe information](#) sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.

Pfizer/COMIRNATY COVID-19 Vaccination Administration Procedures



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1. Review [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#).
2. Pfizer/COMIRNATY COVID-19 vaccine may be supplied in a **PURPLE CAP** formulation or a **GRAY CAP** formulation. The vaccinator should use the formulation according to local protocol & product availability. The vaccinator should be familiar with procedures for preparation, storage & handling of the Pfizer/COMIRNATY formulation they are using. Dosage and clinical indications are the same for both formulations.
 - a. For the **PURPLE CAP** formulation: review the [Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) for COMIRNATY/Pfizer for 12 Years of Age and Older \(PURPLE CAP\)](#).
 - b. For the **GRAY CAP** formulation: review the [Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) for COMIRNATY/Pfizer for 12 Years of Age and Older \(GRAY CAP\)](#)
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.
6. Following the current [CDC Pre-Vaccination Checklist for COVID-19 Vaccines](#), instruct patients accordingly or consult with overseeing provider.
7. Consent must be obtained from the patient or the patient's legally authorized representative 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](#). The following require **written** consent from a parent or legal guardian if vaccinated with COMIRNATY/Pfizer:
 - a. Minors age 12 through 15 years old presenting for primary 2 dose series.
 - b. Minors age 12-17 for 3rd dose of initial series.
 - c. Minors age 12 -17 presenting for booster dose.
 - d. Consent may be obtained verbally for all other ages/situations.
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.
9. **Vaccine Administration:**



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- a. **Ensure the appropriate Pfizer formulation is selected.** The Pfizer/COMIRNATY formulation for ages 12 & up should be selected based on local protocol & product availability. Pfizer COVID-19 vaccine for ages 12 and up (30 µg) will have either:
- i. A **PURPLE CAP** and label. This vaccine must be diluted before use.
 - ii. A **GRAY CAP** and label. This vaccine should **NOT** be diluted before use.

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older ^{1,2}	12 years and older ³	5 through 11 years ⁴ (*Age 5y to <12y on label)
Vial Cap Color			
Dose	30 mcg	30 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL	0.3 mL
Amount of Diluent Needed per Vial ⁵	1.8 mL	NO DILUTION	1.8 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)

- b. Using the formulation for ages 5-11 (10 µg, ORANGE CAP) may result in vaccine administration errors and should not be used in this age group.
- i. If a person aged 12–17 years inadvertently receives a 10µg dose of Pfizer COVID-19 Vaccine (ORANGE cap formulation), the dose does not need to be repeated.
 - ii. If an individual aged 18 years or older inadvertently receives a 10 µg dose (ORANGE cap formulation), the dose should be repeated with the age-appropriate 30 µg dose (PURPLE cap formulation) immediately. Due to the rare risk of myocarditis, males aged <30 years may consider waiting 21 days after the erroneous dose to repeat the dose.
- c. **Preparation:** Prepare vaccine, observing aseptic technique, according to the manufacturer’s instructions. Follow manufacturer’s guidance for storing/handling prepared vaccine.
- i. When using the **PURPLE CAP** formulation, refer to [Pfizer COVID-19 Vaccine Preparation and Administration Summary for 12 & Up \(PURPLE CAP\)](#)
 - ii. When using the **GRAY CAP** formulation, refer to [Pfizer COVID-19 Vaccine Preparation and Administration Summary for 12 & Up \(GRAY CAP\)](#)



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- d. **Vaccine Product and Dosing:**
- i. **First Dose: Administer 0.3 mL** (30 µg) Pfizer/COMIRNATY COVID-19 Vaccine. This vaccine is administered in a 2-dose series. Second doses should be scheduled at least 21 days after first dose.
 - ii. **Second dose: Administer 0.3 mL** (30 µg) Pfizer/COMIRNATY COVID-19 vaccine. Patients shall receive the second COVID-19 vaccine dose of the same brand as first administered. If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. See [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines](#) (“Vaccine Administration” and “Interchangeability of COVID-19 vaccine products” headers). Children who turned from age 11 to age 12 between their first and second doses do not need to repeat a second dose if the 10 µg (ORANGE cap) formulation is given for the second dose.
 - iii. **Third dose of mRNA COVID-19 vaccine for [moderately to severely immunocompromised](#) people: Administer 0.3 mL** Pfizer/COMIRNATY COVID-19 Vaccine. Patients who self-attest to being moderately to severely immunocompromised and have completed a 2-dose mRNA COVID-19 vaccine series can receive a third mRNA COVID-19 vaccine dose of the same product as the primary vaccine series. If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered, if appropriate based on the patient’s age.
 - iv. **Booster dose: Administer 0.3 mL Pfizer/COMIRNATY COVID-19 Vaccine.** Single booster dose should be administered to individuals 12 years and older, no sooner than six 5 months after primary 2-dose series of Pfizer/COMIRNATY. Single booster dose should be administered to individuals 18 years and older, no sooner than ~~six~~ **6 5** months after primary 2-dose series of Moderna. Single booster dose of Pfizer/COMIRNATY COVID-19 Vaccine should be administered to individuals 18 years and older no sooner than two 2 months after primary vaccination with Janssen COVID-19 Vaccine.
 - v. Moderately and severely immunocompromised people over the age of 12 who qualify for a third dose of an mRNA primary series may receive a single COVID-19 booster dose (Pfizer/COMIRNATY, Moderna, or Janssen; as appropriate based on age and assessment



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criteria above). These patients **may receive a total of four COVID-19 vaccine doses.**

- e. **Route of Administration:** Administer Pfizer/COMIRNATY vaccine 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.
- f. **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	1 1/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	1 1/2"	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**).

- g. **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](#).
 - h. **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.
10. **Timing:**
- a. The second dose of COMIRNATY/Pfizer vaccine should be administered as close to the recommended interval as possible, but not earlier than recommended (21 days). However, individuals who receive the second dose up to 4 days before or at any time after the recommended date can be considered fully vaccinated.
 - b. The third dose of COMIRNATY/Pfizer vaccine for moderately and severely immunocompromised people shall be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine



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- series. Third doses administered at least 24 days after completion of the primary series are considered valid and do not need to be repeated.
- c. Booster dose of Pfizer/COMIRNATY COVID-19 Vaccine for the authorized age group should be administered at least 5 months after primary vaccination of Pfizer/COMIRNATY or Moderna vaccine, at least 6 months after primary vaccination of Moderna vaccine, or at least 2 months after Janssen single dose vaccination. There is a 4-day grace period for booster doses; booster doses administer 4 days before the required interval are considered valid and do not need to be repeated.

11. Documentation:

- a. Patient self-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: Document vaccine record in CVMS 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.
- 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/COMIRNATY 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



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Table with 2 columns and 2 rows. Row 1: General instructions for vaccine administration and management of reactions. Row 2: Special Circumstances regarding vaccination outside the US and WHO-EUL vaccines.



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Table with 2 columns: empty left column, right column containing text and numbered list items (3, 4) regarding COVID-19 vaccine administration.



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	<p>moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, if they fall into one of the groups at increased risk for serious complications of COVID-19 or exposure to SARS-CoV-2 as detailed in Considerations for use of a COVID-19 booster dose.</p> <p>d. 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.</p> <p>***Clinical trial participants who did not receive all of 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>
<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 • 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/external/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) 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.



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Table with 2 columns: Category (e.g., Contraindications, Criteria or Circumstances) and Description/Details.

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

This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. This order will expire upon rescission off the State of Emergency Executive Order Number 116. Legal Authority: Executive Order 245.