



**NC State Health Director’s Statewide Standing Order
for COMIRNATY/Pfizer mRNA COVID-19 Vaccine Administration
Revised October 22nd, 2021**

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 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 236](#), 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>Patients 12 years and older who present requesting and have legal and decisional capacity to consent to first or second dose of Primary Series, third dose of Primary Series or Booster dose of Pfizer/COMIRNATY COVID-19 Vaccine.</p> <p><u>Primary 2-Dose Series under the following situations:</u></p> <ul style="list-style-type: none"> • 12 years and older, who present requesting 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"> • 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><u>Booster Dose under the following conditions:</u></p> <ul style="list-style-type: none"> • 65 years or older, who present requesting a booster dose at least 6 months after completion of their primary series of COVID-19 vaccination with Moderna, Pfizer/COMIRNATY, or at least 2 months after single dose primary vaccination with Janssen. • 18 years of age or older, who work in or are long-term care facility residents and present requesting a booster dose at least 6 months after completion of their primary series of COVID-19 vaccination with Moderna or Pfizer/COMIRNATY or at least 2 months after completion of single dose primary COVID-19 vaccination with Janssen. • 18 or older who self-attest to an individual benefit of receiving a booster dose over a risk of receiving one and who have: <ul style="list-style-type: none"> ➢ an <u>underlying medical condition that puts them at high risk for severe COVID-19</u> and present requesting a booster dose at least 6 months after completion of their primary series of COVID-19 vaccination with Moderna or Pfizer/COMIRNATY or at least 2 months after completion of primary single dose primary COVID –19 vaccination with Janssen OR ➢ an occupational or institutional exposure to COVID 19 (see the <u>CDC’s examples of workers who may be eligible</u>) and present requesting a booster dose at least 6 months after completion of their primary series of COVID-19 vaccination with Moderna or Pfizer/COMIRNATY or at least 2 months



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	<p>after completion of primary single dose primary COVID –19 vaccination with Janssen.</p> <p>*Regarding booster doses: patients can receive any brand of COVID-19 vaccine for their booster shot, upon their request.</p> <p>Patients will be vaccinated under the following conditions:</p> <ol style="list-style-type: none"> 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. 2. Patients (recipients of vaccine) 12 – 15 years of age who present requesting COMIRNATY/Pfizer for the first 2 dose series or patients (recipients of vaccine) 12 – 17 years of age who present requesting COMIRNATY/Pfizer for a 3rd dose in primary series due an immunocompromised conditions and whose parent or legal guardian has consented to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status.
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Assessment Criteria

Assessment Criteria	<p>Patients shall be vaccinated with COMIRNATY/Pfizer COVID-19 Vaccine based on:</p> <ol style="list-style-type: none"> 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. See the below chart for minimum intervals between doses: <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td>Dose 1 to Dose 2 of COMIRNATY/ Pfizer</td> <td>*Dose 2 to Dose 3 of COMIRNATY/ Pfizer</td> <td>**End of primary series of COMIRNATY/ Pfizer or Moderna to booster dose of COMIRNATY/ Pfizer</td> <td>**End of primary series of Janssen to booster dose of COMIRNATY/ Pfizer</td> </tr> <tr> <td align="center">21 days</td> <td align="center">28 days</td> <td align="center">6 months</td> <td align="center">2 months</td> </tr> </table> <p>* see the section above on third doses to determine if a three-dose primary series is appropriate. **see the section above on booster doses to determine if a booster dose is appropriate after completion of the COMIRNATY/Pfizer, Moderna, or Janssen primary series.</p>	Dose 1 to Dose 2 of COMIRNATY/ Pfizer	*Dose 2 to Dose 3 of COMIRNATY/ Pfizer	**End of primary series of COMIRNATY/ Pfizer or Moderna to booster dose of COMIRNATY/ Pfizer	**End of primary series of Janssen to booster dose of COMIRNATY/ Pfizer	21 days	28 days	6 months	2 months
Dose 1 to Dose 2 of COMIRNATY/ Pfizer	*Dose 2 to Dose 3 of COMIRNATY/ Pfizer	**End of primary series of COMIRNATY/ Pfizer or Moderna to booster dose of COMIRNATY/ Pfizer	**End of primary series of Janssen to booster dose of COMIRNATY/ Pfizer						
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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. 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 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. <hr/> <p>Pfizer/COMIRNATY COVID-19 Vaccination Administration Procedures</p> <ol style="list-style-type: none"> 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 COMIRNATY/Pfizer. 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. Minors age 12 through 15 years old require written consent from a parent or legal guardian if vaccinated with COMIRNATY/Pfizer as primary 2 dose series or minors



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	<p>age 12-17 for 3rd dose of initial series. Consent may be obtained verbally for all other ages.</p> <p>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.</p> <p>9. Vaccine Administration:</p> <ul style="list-style-type: none">a. Preparation: Mix, observing aseptic technique, according to the manufacturer’s instructions. Follow manufacturer’s guidance for storing/handling mixed vaccine. Refer to: Pfizer COVID-19 Vaccine Preparation and Administration Summaryb. Vaccine Product and Dosing:<ul style="list-style-type: none">i. First Dose: Administer 0.3 mL 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 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).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.iv. Booster dose: Administer 0.3 mL Pfizer/COMIRNATY COVID-19 Vaccine. Single booster dose should be administered per assessment criteria above no sooner than six 6 months after primary 2-dose series of Moderna or Pfizer/COMIRNATY. Single booster dose of Pfizer/COMIRNATY COVID-19 Vaccine should be administered per assessment criteria above no sooner than two 2 months after primary vaccination with Janssen COVID-19 Vaccine.c. Route of Administration: Administer Pfizer/COMIRNATY vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 12
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years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used.

- d. **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**).

- e. **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](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html). <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- f. **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.

12. **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 series.
- c. Booster dose of Pfizer/COMIRNATY COVID-19 Vaccine (per conditions above) should be administered at least 6 months after primary vaccination



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of Moderna or Pfizer/COMIRNATY vaccine or at least 2 months after Janssen single dose vaccination.

13. **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 vaccine or injectable therapy
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) should be observed for 30 minutes following vaccination.
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.



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	<p>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.</p>
<p>Special Circumstances</p>	<p>Patients vaccinated with COVID-19 vaccines not authorized or approved in the United States: These patients require a medical consultation. Limited data are available on the safety or efficacy of receiving a COVID-19 vaccine currently authorized or approved in the United States after receipt of a non-FDA-authorized or non-FDA-approved COVID-19 vaccine. However, in some circumstances people who received a COVID-19 vaccine not currently authorized or approved in the United States may be offered revaccination with an FDA-authorized or FDA-approved vaccine:</p> <ol style="list-style-type: none"> 1. COVID-19 vaccines not authorized or approved by FDA but listed for emergency use by World Health Organization (WHO): <ol style="list-style-type: none"> a. Patients who completed a COVID-19 vaccination series with a vaccine that has been listed for emergency use by the WHO do not need any additional doses with an FDA-authorized or FDA-approved COVID-19 vaccine. b. Patients who are partially vaccinated with a COVID-19 vaccine series listed for emergency use by WHO may be offered a complete FDA-authorized or a FDA-approved COVID-19 vaccine series. Wait at least 28 days after the last dose of a non-FDA-authorized or non-FDA-approved vaccine or a WHO-listed vaccine before administering an FDA-authorized or FDA-approved COVID-19 vaccine. 2. COVID-19 vaccines not authorized or approved by FDA or not listed for emergency use by WHO: Patients who completed or partially completed a COVID-19 vaccine series with a vaccine that is not authorized or approved by FDA or not listed for emergency use by WHO may be offered a complete FDA-authorized or complete FDA-approved COVID-19 vaccine series. Wait at least 28 days after the last dose of a non-FDA-authorized or a non-FDA-approved vaccine or a WHO-listed vaccine before administering an FDA-authorized or FDA-approved COVID-19 vaccine. 3. Administration of an FDA-authorized or FDA-approved COVID-19 vaccine in these patients should comply with all conditions of use specified under the EUA or FDA approval for the vaccine being used.
<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



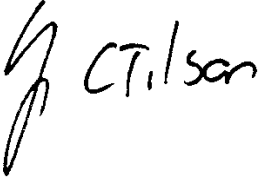
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	<p>Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/external/icon or by calling 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. 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.
<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 Appendix C: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States.</p>
<p>Criteria or Circumstances for Notifying Medical Provider</p>	<ol style="list-style-type: none"> 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 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. 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.



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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Handwritten signature of Elizabeth Cuervo Tilson.

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

Date Signed: __10-22-21_____

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 236](#)..