



**NC State Health Director’s Statewide Standing Order  
for COMIRNATY/Pfizer and Moderna mRNA COVID-19 Vaccine Administration  
Revised August 31, 2021**

**Purpose:** To meet the goal of administering FDA-approved (COMIRNATY), FDA-Emergency Use Authorization (PFIZER BioNTech) herein-after COMIRNATY/Pfizer, or FDA-Emergency Use Authorization Moderna COVID-19 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 193](#), 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 through an Emergency Use Authorization (EUA) and per conditions of this order.

<b>COVID-19 Vaccination</b>		
<b>Condition or Situation</b>	<b>COMIRNATY/Pfizer</b>	<b>Moderna</b>
	<ol style="list-style-type: none"> <li>Patients (recipients of vaccine) 16 – years of age or older who present requesting COMIRNATY/Pfizer vaccine and have legal and decisional capacity to consent to the vaccine will be vaccinated under FDA approved status.</li> <li>Patients (recipients of vaccine) 12 – 15 years of age who present requesting COMIRNATY/Pfizer and whose parent or legal guardian has consented to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status.</li> </ol>	Patients (recipients of vaccine), 18 years of age and older, present requesting and consent to <b>Moderna COVID-19 Vaccine</b> and have legal and decisional capacity to consent to the vaccine.
<b>Assessment Criteria</b>		
<b>Assessment Criteria</b>	<b>COMIRNATY/Pfizer</b>	<b>Moderna</b>
	Patients shall be vaccinated with COMIRNATY/Pfizer COVID-19 Vaccine based on: <ol style="list-style-type: none"> <li>the conditions of this order</li> <li>no history of complete 2-dose COVID-19 vaccination, regardless of brand.</li> </ol>	Patients shall be vaccinated with Moderna COVID-19 Vaccine based on: <ol style="list-style-type: none"> <li>the conditions of this order</li> <li>no history of complete 2-dose COVID-19 vaccination, regardless of brand.</li> </ol>
<b>Plan of Care</b>		
<b>Actions</b>	<b>COMIRNATY/Pfizer</b>	<b>Moderna</b>
	<b>Patient Education and Data Collection</b>	<b>Patient Education and Data Collection</b>



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	<p>a. 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> <ul style="list-style-type: none"> <li>i. Where, how, and when to obtain the <b>second</b> COVID-19 vaccination.</li> <li>ii. CDC Pre-Vaccination Checklist for COVID-19 Vaccine</li> <li>iii. Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (Covid-19 Vaccine, MRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)</li> <li>iv. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.</li> </ul> <p>Note: Providers need to assure the most current versions of the documents listed above by visiting: <a href="https://www.cvdvaccine-us.com/">https://www.cvdvaccine-us.com/</a></p>	<p>a. 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> <ul style="list-style-type: none"> <li>i. Where, how, and when to obtain the <b>second</b> COVID-19 vaccination.</li> <li>ii. CDC Pre-Vaccination Checklist for COVID-19 Vaccine</li> <li>iii. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older</li> <li>iv. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.</li> </ul> <p>Note: Providers need to assure the most current versions of the documents listed above by visiting: <a href="https://www.modernatx.com/covid19vaccine-eua/providers/">https://www.modernatx.com/covid19vaccine-eua/providers/</a></p>
<p><b>Content Below Applies to Both COMIRNATY/Pfizer and Moderna COVID-19 Vaccines</b></p>		
<p><b>3. COVID-19 Vaccination Administration Procedures</b></p> <ul style="list-style-type: none"> <li>a. Review Interim Clinical Considerations for Use of COVID-19 vaccines - <a href="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</a></li> <li>b. Review the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for both <a href="#">COMIRNATY/Pfizer</a> and <a href="#">Moderna</a>.</li> <li>c. 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.</li> </ul>		



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- d. 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.
- e. Review [Precautions](#), [Contraindications](#), and [Criteria or Circumstances for Notifying Medical Provider](#) sections of this standing order **before** administering the COVID-19 vaccine.
- f. Review the patient-completed [CDC Pre-Vaccination Checklist for COVID-19 Vaccines](#).
- g. Following the current [CDC Pre-Vaccination Checklist for COVID-19 Vaccines Information for Healthcare Providers](#), instruct patients who present under the following conditions:
  1. If a patient indicates they are feeling sick on the Pre-Vaccination Checklist, ask them if they have a moderate to severe illness. If patient says yes, consult the medical provider.
  2. Patients with a history of myocarditis or pericarditis prior to COVID-19 vaccination or after receipt of the first dose of a mRNA COVID-19 vaccine series but before administration of the second dose, require consultation with the medical provider.
  3. Instruct patients with bleeding disorders or who take blood thinners
    - a. they may have increased bleeding after intramuscular injection, and
    - b. to call their primary care provider or seek other medical care if the injection site starts bleeding after leaving the vaccination clinic and cannot be stopped by applying pressure.
  4. Instruct patients who have received passive antibody therapy as a treatment for COVID-19 that COVID-19 vaccination will be deferred for at least 90 days since their last treatment as a precautionary measure to avoid interference of the antibody treatment with vaccine-induced immune responses.
  5. Instruct patients with known current symptomatic SARS-CoV-2 infection their vaccine will be deferred until the patient has recovered from the acute illness and criteria have been met for them to discontinue isolation.
  6. Instruct patients who are immunocompromised that:
    - a. COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
    - b. Data suggest the immune response to COVID-19 vaccination might be reduced in some immunocompromised people and the need to continue to follow all current guidance to protect themselves against COVID-19 including wearing a mask, staying 6 feet apart from others they do not live with, avoiding crowds and poorly ventilated



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	<p>indoor spaces until advised otherwise by their healthcare professional. Close contacts of immunocompromised people should also be strongly encouraged to be vaccinated against COVID-19 to protect immunocompromised people.</p> <p>c. Immunocompromised patients who have completed an initial 2-dose primary mRNA COVID-19 series and self-attest to a moderate to severe immune compromise can receive a third dose of mRNA. Conditions that would be considered to result in a moderate or severe compromise are described on the CDC website <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html</a></p> <p>7. Instruct patients that COVID-19 vaccines are recommended for people who are pregnant or lactating (breastfeeding), trying to get pregnant or might become pregnant in the future. Educate the patient that pregnant women with COVID-19 have an increased risk of severe illness, are at increased risk for preterm birth and might be at increased risk for other adverse pregnancy complications and outcomes, such as preeclampsia, coagulopathy, and stillbirth.</p> <p>8. Instruct patients with dermal fillers that they may develop temporary swelling at or near the filler injection site, usually face or lips, after a dose of an COVID-19 vaccine. Administer vaccines to persons with injectable dermal fillers who have no contraindications or precautions to vaccination. These persons should be advised to contact their healthcare provider if swelling develops at or near the site of dermal filler following vaccination.</p> <p>9. Instruct patients with a history of allergic reactions, including severe allergic reactions, NOT related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), that these are NOT contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. Inform these patients that there are unknown risks of developing a severe allergic reaction and they will be observed for any signs of allergic reaction after vaccination. Inform patients who have a history of anaphylaxis they will be observed for 30 minutes and other people for 15 minutes.</p> <p>10. Instruct patients that persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to the other (e.g., mRNA-COMIRNATY/Pfizer or Moderna) because of potential cross-reactive hypersensitivity. Consultation with an allergist 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.</p>
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	<p>11. Instruct patients with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A), there are no data on the safety and efficacy of COVID-19 vaccines in patients with a history of multisystem inflammatory syndrome. The mechanism of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. It is unclear if people with a history of MIS-C or MIS-A are at risk for recurrence of the same dysregulation immune response following reinfection with SARS-CoV-2 or in response to vaccination. Inform the patient that the CDC recommends considering delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis. Inform the patient and/or their guardians that they may want to have a conversation with their clinical team or a specialist to assist with decisions about the use of a COVID-19 vaccine, though a conversation with a healthcare provider is not required before vaccination.</p> <p>4. 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 <a href="#">NC General Statute. 90-21.13</a> and <a href="#">NC General Statute 90-21.5</a> and <a href="#">Session Law 2021-110</a>. Minors age 12 through 15 years old require <b>written</b> consent from a parent or legal guardian if vaccinated with COMIRNATY/Pfizer. Consent may be obtained verbally for all other ages.</p> <p>5. <u>Personal Protective Equipment</u>: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per <a href="#">CDC guidelines for COVID-19 vaccinations</a> to protect against the transmission of COVID-19.</p> <p>6. <u>Vaccine Preparation and Administration</u>:</p> <p>a. <b>Preparation</b>: Mix, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine. Refer to: <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html">https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html</a></p> <p>b. <b>COMIRNATY/Pfizer COVID-19 Vaccine Administration</b>: Administer 0.3 mL Pfizer-BioNTech COVID-19 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. This vaccine is administered in a 2-dose series. Second doses should be scheduled at 21 days after first dose. Refer to #4 above for consent requirements.</p> <p>c. <b>Moderna COVID-19 Vaccine Administration</b>: Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 18 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used. This vaccine is administered in a 2-dose series. Second doses should be scheduled at 28 days after first dose.</p> <p>d. <b>Second dose of COVID-19 vaccine</b>:</p> <p>i. <b>Vaccine product</b>: Patients shall receive the second COVID-19 vaccine dose of the same brand as first administered. Also, if two</p>
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	<p>doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. See “Vaccine Administration” and “Interchangeability of COVID-19 vaccine products” headers: <a href="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</a></p> <p>ii. <b>Timing of second dose:</b> The second dose of COMIRNATY/Pfizer and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks - COMIRNATY/Pfizer or 1 month (28 days) - Moderna). 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.</p> <p><b>e. Third dose of mRNA COVID-19 vaccine for moderately and severely immunocompromised people:</b></p> <p>i. Patients who self-attest to being moderately to severely immunocompromised and have completed a mRNA COVID-19 vaccine series can receive a third mRNA COVID-19 vaccine dose of the same product as the initial 2-dose mRNA COVID-19 primary vaccine series (COMIRNATY/Pfizer or Moderna). 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. A person should not receive more than three mRNA COVID-19 vaccine doses.</p> <p>ii. <b>All</b> minors who are moderately to severely immunocompromised require <b>written</b> consent from a parent or legal guardian when vaccinated with a third dose of COMIRNATY/Pfizer per <a href="#">Session Law 2021-110</a>.</p> <p>iii. Conditions that would be considered to result in a moderate or severe compromise are described on the CDC website <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html</a></p> <p>iv. The third dose of COMIRNATY/Pfizer or Moderna vaccines 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.</p> <p>v. Documentation of patient self-attestation to severe or moderate immunocompromise should be done during administration within the notes section by the healthcare worker administering the dose in CVMS or comparable section of an EHR or other documenting systems.</p>
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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 than 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

g. 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 at: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

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.

i. **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 (<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>) for the following time periods:

i. 30 minutes:

- Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy
- 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-COMIRNATY/Pfizer or Moderna) should be observed for 30 minutes following vaccination.

ii. 15 minutes: All other persons



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- h. **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. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>
- i. **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.
- j. **Patients vaccinated with COVID-19 vaccines not authorized or approved in the United States:** These patients require a medical consultation. No 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:
- i. COVID-19 vaccines not authorized or approved by FDA but listed for emergency use by World Health Organization (WHO)
    - 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.
    - 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 FDA-approved COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-FDA-authorized or non-FDA-approved vaccine before administering an FDA-authorized or FDA-approved COVID-19 vaccine.
  - ii. 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 the non-FDA-authorized or non-FDA-approved vaccine before administering an FDA-authorized or FDA-approved COVID-19 vaccine.





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	<p>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> <p>k. <b>CVMS:</b> Document vaccine record in CVMS <b>within 24 hours</b> after vaccine administration per system guidelines found at: <a href="https://immunize.nc.gov/providers/covid-19training.htm">https://immunize.nc.gov/providers/covid-19training.htm</a>. If vaccine is documented in the EHR within 24 hours, providers have <b>no more than 72 hours</b> from administration to also enter data in CVMS.</p> <p>l. <b>Electronic Medical Record:</b> If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.</p> <p>m. Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacture, lot number, date of vaccination, name/location of vaccinator and clinic site.</p> <p>n. Counsel when and how patient needs to schedule return appointment for second dose of COVID-19 vaccine, if applicable.</p>
<p><b>Follow-up</b></p>	<p>1. Vaccinators administering COVID-19 vaccine must report the following information associated with the administration of the vaccine in accordance with each manufacturer’s fact sheets for healthcare providers administering vaccine: COMIRNATY/Pfizer: <a href="https://www.cvdvaccine-us.com/">https://www.cvdvaccine-us.com/</a> Moderna: <a href="https://www.modernatx.com/covid19vaccine-eua/providers/dosing-administration">https://www.modernatx.com/covid19vaccine-eua/providers/dosing-administration</a></p> <ol style="list-style-type: none"> <li>1. Vaccine administration errors, whether associated with an adverse event or not</li> <li>2. Serious adverse events (irrespective of attribution to vaccination)</li> <li>3. Cases of Multisystem inflammatory syndrome in <u>children</u> and <u>adults</u></li> <li>4. Cases of COVID-19 that result in hospitalization or death</li> </ol> <p>Complete and submit reports to VAERS online at: <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>. For further assistance with reporting to VAERS, please email <a href="mailto:info@VAERS.org">info@VAERS.org</a> or call 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA or “Moderna COVID- 19 Vaccine EUA” as appropriate in the report's description section.</p> <p>Vaccinators are required to follow the instructions in the letter issued by the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for emergency use of COVID-19 for both Pfizer-BioNTech COVID-19 Vaccine and Moderna Vaccine. Pfizer letter: <a href="https://www.fda.gov/media/144412/download">https://www.fda.gov/media/144412/download</a> Moderna letter can be found here: <a href="https://www.fda.gov/media/144636/download">https://www.fda.gov/media/144636/download</a></p>
<p><b>Precautions for Use of this Order</b></p>	<p>i. History of an immediate allergic reaction to any other vaccine or 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 reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.</p>

