NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
Administration of monovalent Moderna COVID-19 Vaccine and SPIKEVAX mRNA in Individuals 12 Years of Age and Older
Original August 5, 2022; updated September 7, 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 Moderna COVID-19 vaccine or SPIKEVAX

NOTE: On August 31, 2022, the FDA rescinded use of the monovalent Moderna COVID-19 vaccine/SPIKEVAX vaccine as a booster for persons 12 years of age and older. Eligible patients who request and are eligible for a Moderna booster should receive a bivalent COVID-19 booster.

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 2022-72, 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 approved or authorized by the FDA per conditions of this order.

COVID-19 Vaccination	
Condition/Situation : Non-immunocompromised Patients (most patients)	**NOTE:** This standing order pertains only to: 1) Moderna COVID-19 Vaccine supplied in a multiple –dose vial with a red cap and a label with a light blue boarder which is authorized for use to provide: • a two-dose primary series to individuals 12 years of age and older; and • third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise. **AND** 2) SPIKEVAX (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by ModernaTX, Inc. that is indicated for active immunization to prevent COVID-19 in individuals 18 years of age and older. It is approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 18 years of age and older. It is also authorized for emergency use to provide: • • a two-dose primary series to individuals 12 years through 17 years of age; and • a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromised. SPIKEVAX (COVID-19, mRNA) and Moderna COVID-19 Vaccine supplied in multiple dose vials with a red cap and a label with a light blue border intended for use in individuals 12 years of age and older should not be used in individuals 6 months through 11 years of age because of the potential for vaccine administration errors, including dosing errors. The FDA-licensed SPIKEVAX® COVID-19 vaccine and the Moderna COVID-19 vaccine are authorized vaccine have the same formulation and can be used interchangeably without presenting any safety or effectiveness concerns. However, persons 12-17 should be documented as receiving Moderna COVID-19 vaccine.

CDC recommends that people stay up to date with COVID-19 vaccination. Patients who are NOT immune compromised and present requesting vaccination will receive, with appropriate consent:

Primary Series (2-Dose Moderna/ SPIKEVAX):

- 12 years and older, who present requesting Moderna vaccine for the first or second dose of 2-dose primary series. The second dose shall be given 4 – 8 weeks after the first dose. Complete all primary series using the same mRNA vaccine product (Interim COVID-19 Immunization Schedule for 6 Months of Age and Older).
- While a 4-week interval remains optimal for moderately to severely immunocompromised persons, adults ages 65 years and older, and others who need rapid protection because of community transmission or risk of disease, an 8-week interval may be optimal for some people, including males 12-39 years of age because of the small risk of myocarditis associated with mRNA COVID-19 vaccines. Vaccine effectiveness may also be increased with an interval longer than 4 weeks.
- People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination, including booster vaccination, at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Interval for Dose 1 to Dose 2 of Primary Series Moderna/SPIKEVAX	**4 – 8 weeks***

*For more information on counseling patients on the interval between doses 1 and 2, see Considerations for intervals for mRNA COVID-19 vaccine primary series.

Condition/Situation: Moderately to Severely Immunocompromised patients

Patients who self-attest to being moderately to severely immunocompromised, who present requesting and have legal capacity to consent, shall receive:

➢ **Primary Series (3-dose Moderna/SPIKEVAX):**

12 years and older, requesting Moderna/SPIKEVAX vaccine for the first, second, or third dose of their 3-dose primary series of mRNA vaccine. (See appropriate interval between doses in table below).

(Table 4)

Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People	
Dose 1 to Dose 2 of Moderna/SPIKEVAX	4 weeks*
Dose 2 to Dose 3 Moderna/SPIKEVAX	At least 4 weeks

*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.

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	➢ **Additional (2nd) Dose after receiving Janssen vaccine (Moderna/SPIKEVAX):** 18 years and older, presenting for Moderna vaccine at least 28 days after receiving their first dose of Janssen COVID-19 vaccine. **The additional dose is considered part of the primary series and is NOT a booster dose. **(Table 5)** **Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People** **1st dose of Janssen vaccine to additional dose of Moderna/SPIKEVAX** — 4 weeks *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 Moderna/SPIKEVAX, refer to section on "Special Circumstances."
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Moderna/SPIKEVAX COVID-19 Vaccine based on: 1. The conditions/situations of this order (see above). 2. If patient is presenting for first dose of Moderna/SPIKEVAX: ensure there is no history of previous COVID-19 vaccination, regardless of brand. 3. If patient is presenting for second, third, or additional dose of Moderna/ SPIKEVAX**:** ensure that the minimum interval between doses has been met regardless as to whether the patient is immunocompromised or not. (see appropriate Tables above or CDC COVID- 19 Immunization Schedule for further guidance).
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. Review CDC Pre-Vaccination Checklist for COVID-19 Vaccine 2. If the patient is presenting for dose 1 of their primary series; provide education on optimal vaccine intervals so that the patient can choose when they would like to return for their second shot. a. A four-week interval between dose 1 and dose 2 is the minimum interval between these doses and provides more rapid protection against COVID-19. A four-week interval is recommended for:

i. People who self-attest to being moderately to severely immunocompromised
ii. Adults aged 65 and older
iii. People who self-attest to having an underlying medical condition which may put them at higher risk of severe COVID-19; such as the examples from the CDC'S list of People with Certain Medical Conditions

b. Considerations for intervals for mRNA COVID-19 vaccine primary series.
i. A 3- or 4-week interval continues to be the recommended interval for people who are moderately or severely immunocompromised, adults ages 65 years and older, and in situations when the fullest possible protection needs to be achieved sooner. Some people may benefit from an 8-week interval between dose 1 and dose 2, as it may reduce the risk of myocarditis and may increase peak antibody response/ vaccine effectiveness. An 8-week interval may be optimal for:
ii. Males aged 12-39, who do not fall into one of the above categories.
iii. All patients, aged 12-64, who do not fall into one of the above categories.

3. Fact Sheet for Recipients and Caregivers for SPIKEVAX and Moderna 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 CDC COVID-19 Vaccine Boosters for latest information.
5. V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.

Moderna COVID-19 Vaccination Administration Procedures

1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States
2. Review Fact Sheet for Healthcare Providers Administering Vaccine
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 by 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. 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. Patients ***should*** delay taking EVUSHELD for two weeks after COVID-19 vaccination.
8. 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.
9. 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:

Patients should 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. *When a patient inadvertently receives an incorrect/ inappropriate dose of COVID-19 vaccine, review Interim Clinical Considerations, Appendix C for COVID-19 vaccine errors and deviations, and take action as directed.

Vaccine presentation:

Authorized Age Group	**12 years & older**
Vial Cap Color	**Red**
Label Border Color	**Light Blue**
Dose	**100 mcg**
Injection Volume	**0.5 ml**
Dilution Required	**NO**

Doses per Vial	**Maximum 11**

1. **Vaccine Preparation**:
Follow manufacturer's guidance for storing/handling mixing vaccine. Refer to: Moderna COVID-19 Vaccine Preparation and Administration Summary. In general, the same mRNA vaccine product should be used for all doses in the primary series. See CDC guidance for exceptional situations.

2. **Dosing:**

Moderna/SPIKEVAX COVID-19 Vaccine Dosing	
Primary series: **Dose 1, 2 or 3**	**Red** top **light blue border** 0.5mL 100mcg

3. **Timing:**
   a. All recommended doses of Moderna COVID-19 vaccine/SPIKEVAX shall be administered as close to the recommended interval as possible. More information on timing is available in the CDC Interim Clinical Considerations guidance. 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 4 & 5)
   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), they should receive the vaccine product and dosage for the older age group for all subsequent doses. For specific guidance see CDC Interim Clinical Considerations on Transitioning from a younger to older age group.
4. **Administration:**
   a. **Route of Administration:** Administer Moderna/SPIKEVAX vaccine via 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.

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. Patients may self-report their weight for needle selection purposes. See needle sizing charts below (Children 12-18 years and sizing for adults (by weight):

Needle Sizing for Children 12-18 years			
Age of Patient	**Needle Gauge**	**Needle Length**	**Injection Site**
Children 12-18 years	16-25 mm	*5/8 inch-1 inch	Deltoid muscle

Needle Sizing for Adults			
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
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle
Female 152–200 lbs.	22–25	1-11/2"	Deltoid muscle
Male 153–260 lbs.	22–25	1-11/2"	Deltoid muscle
Female 200+ lbs.	22–25	11/2"	Deltoid muscle
Male 260+ lbs.	22–25	11/2"	Deltoid muscle

* 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**).

c. **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 on Coadministration of COVID-19 vaccines with other vaccines.

d. **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.

5. **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/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 follow up of COVID-19 vaccine, if applicable.
	Moderna/ SPIKEVAX COVID-19 Vaccination Observation and Follow-Up 1. **Post-vaccination Observation**: 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 CDC Interim Considerations - Routine observation periods following COVID-19 vaccination and Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination 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 vaccine-COMIRNATY/Pfizer or Moderna) should be observed for 30 minutes following vaccination. iv. Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy

	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. See Early Recognition and Management of Anaphylaxis. 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.
Special Circumstances	**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. **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. • Moderately or severely immunocompromised clinical trial participants should receive an additional dose of Pfizer-BioNTech COVID-19 Vaccine (ages 12 years and older) or Moderna COVID-19 Vaccine (ages 18 years and older) 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. Clinical trial participants (including moderately or severely immunocompromised people who received a 3-dose Pfizer primary series) **should** receive a single bivalent booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (ages 12 years and older) or Moderna COVID-19 Vaccine, Bivalent (ages 18 years and older), unless they have received or plan to receive a booster dose through a clinical trial. 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.

	For more information, refer to Interim Clinical Considerations, Appendix B (People who received COVID-19 vaccine as part of a clinical Trial) outside the United States)
Follow-up	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: • Vaccine administration errors ○ Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix C. Vaccine administration errors and deviations • Serious adverse events • Cases of Multisystem Inflammatory Syndrome • Cases of COVID-19 that result in hospitalization or death 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.
Precautions for Use of this Order	Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine. See CDC Contraindications and Precautions for COVID-19 Vaccination 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 after a dose of an **mRNA or Novavax COVID-19 vaccine**.

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	6. Persons with a history of MIS-C or MIS-A.
Contraindications for Use of this Order	Do not administer the COVID-19 Vaccine to individuals with a history of: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine History of a known diagnosed allergy to a component of the COVID-19 vaccine • Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. See Contraindications and Precautions for COVID-19 Vaccination
Criteria or Circumstances for Notifying Medical Provider	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. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 7. 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. Note: Healthcare providers or health departments in the United States can request a consultation from CISA COVID for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

Approved by: ___ CTilson _____ Date Signed: __9-8-22_____

Elizabeth Cuervo Tilson, MD, MPH
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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 2022-72, 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.