NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
Administration of Moderna COVID-19 Vaccine Bivalent Booster Original and Omicron BA.4 /BA. 5 in Individuals 6 Years of Age and Older
September 2, 2022; Revised October 12, 2022; Revised January 31, 2023

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, Bivalent (Original and Omicron BA.4/BA.5), herein referred to Moderna COVID-19 Vaccine, Bivalent.

NOTE: On September 1, 2022, CDC recommended the use of Moderna COVID-19 Vaccine Bivalent Original and Omicron BA.4/BA.5 as authorized by FDA EUA on August 31, 2022 for persons 18 and older. On October 12, the FDA and CDC lowered the authorized age to 6 years of age for administration of the Moderna COVID-19 Vaccine Bivalent Original and Omicron BA.4/BA.5.

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-74, Sec. 9G.7.(a)-(e) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines approved or authorized by the FDA per conditions of this order.

NOTICE: On January 26, 2023, the FDA revised the EUA for EVUSHELD and rescinded authorization for use in the United States until further notice by the agency. EVUSHELD is no longer effective against the most prevalent circulating strains of SARS CoV2. Therefore, any recommendations for use as a therapeutic for COVID-19 have been removed from this standing order.

COVID-19 Vaccination	
Condition/Situation :	The Moderna COVID-19 Vaccine, Bivalent is **authorized** by FDA EUA for use in persons 6 years and older who have completed a primary series of COVID-19 vaccines or have had at least one authorized or approved COVID-19 booster vaccine. Patients who have completed a primary series of any COVID 19 vaccination shall receive: One dose of Moderna COVID-19 Vaccine, Bivalent **if** the • Interval between last dose of primary series and Moderna Vaccine, Bivalent has been at least 2 months **or** • Interval between last booster dose of any previously authorized or approved COVID-19 booster vaccine and ModernaCOVID-19 Vaccine, Bivalent has been at least 2 months.
Assessment Criteria	
Assessment Criteria	• Patients shall be vaccinated with Moderna COVID-19 Vaccine, Bivalent based on the conditions/situations of this order (see above). • Ensure the minimum interval between last primary dose or last booster dose has been met for the dose patient is to receive.

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	• Persons 6-17 years of age must have written consent from the legally authorized representative prior to vaccine administration per agency policy and in accordance with NC General Statute. 90-21.13. For persons 18 and older, consent must be obtained per NC General Statute 90 21.13.
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. Provide Fact Sheet for Recipients and Caregivers for **Moderna COVID-19 Vaccine Bivalent Original and Omicron BA.4 /BA. 5 in Individuals 6 Years of Age and Older** 3. V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.
	Moderna COVID-19 Vaccine, Bivalent Vaccination Administration Procedures 1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States 2. Review CDC EUA for Healthcare Providers of Moderna COVID-19 Vaccine Bivalent Original and Omicron BA.4 /BA. 5 in Individuals 6 Years of Age and Older 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 Moderna Bivalent 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 bivalent COVID-19 booster vaccine.

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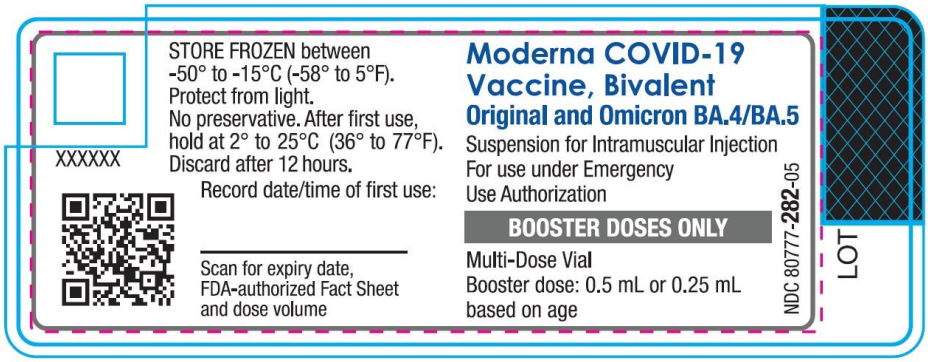
6. Following the current CDC Pre-Vaccination Checklist for COVID-19 Vaccines, instruct patients accordingly or consult with overseeing provider.
    a. The pre-vaccination checklist shall be followed with the following exception: COVID-19 vaccination should ***not*** be deferred in patients who received monoclonal antibody treatment or convalescent plasma. ~~Patients ***should*** delay taking EVUSHELD for two weeks after COVID-19 vaccination.~~
7. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per CDC guidelines for COVID-19 vaccinations to protect against the transmission of COVID-19.

Vaccine Product & Preparation:

1. **Vaccine Preparation**: Follow the same manufacturer's guidance for storing/handling vaccine as with previous Moderna vaccine products. Refer to: Moderna COVID-19 Vaccine Preparation and Administration Summary.
2. **Presentation**:



3. **Dosing:**
    a. For patients 12 and older administer:0.5 ml/50 mcg/dose
    b. For patients 6 through 11 administer: 0.25 ml/50mcg/dose

4. **Timing:**
    a. Timing (interval) between last dose of a COVID-19 primary series shall be at least 2 months.
    b. Timing (interval) between last dose of a COVID-19 booster vaccine shall be at least 2 months.
5. **Administration:**

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a. **Route of Administration:** Administer vaccine via intramuscular (IM) injection in the deltoid muscle of the arm. 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.

Needle Sizing for Children 6-18 years

Age of Patient	Needle Gauge	Needle Length	Injection Site
6-10 years old	22-25g	*5/8-1 inch	Deltoid muscle
	22-25g	**1-1.25 inches**	**Anterolateral thigh**
11-18 years old	22-25g	*5/8-1 inch	Deltoid muscle
	22-25g	**1-1.25 inches**	**Anterolateral thigh**

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

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	following guidance in the CDC Interim Clinical Considerations on Coadministration of COVID-19 vaccines with other vaccines. 6. **Documentation:** a. **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. b. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy. c. 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.
	Moderna COVID-19 Vaccine, Bivalent 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

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	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, particularly 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 and whether the primary series was completed. Refer to Interim Clinical Considerations, Appendix B (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. *The following persons require medical consultation. If clinical trial participants have questions about whether they should receive a bivalent 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 C (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 E. Vaccine administration errors and deviations • Serious adverse events • Cases of Multisystem Inflammatory Syndrome • Cases of COVID-19 that result in hospitalization or death

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	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 the Moderna COVID-19 Vaccine, Bivalent 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 history of myocarditis or pericarditis after a dose of an **mRNA or Novavax COVID-19 vaccine**. 5. Persons with a history of MIS-C or MIS-A. 6. 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.
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

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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: _10-12-2022_____

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 2022-74, Sec. 9G.7.(a)-(e) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.