NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order for FDA Authorized Novavax COVID-19 Vaccine (2024-2025 Formula) Administration
September 13, 2024

Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons 12 years of age and older who meet the criteria established by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and to administer Novavax COVID-19 Vaccine (2024-2025 Formula) to persons who meet criteria set-forth by the Food and Drug Administration in accordance with FDA Emergency Use Authorization.

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) and Session Law 2023-65, Sec. 9G.7 (to extend authorization through December 31, 2024) 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.

COVID-19 Vaccination	
Condition/Situation	Note: Novavax COVID-19 Vaccine (2024-2025 Formula) is under an Emergency Use Authorization. **Individuals 12 Years of Age and Older Who Are Not Moderately or Severely Immunocompromised** who present requesting vaccination with Novavax COVID-19 Vaccine (2024-2025 Formula) will receive the following based on previous vaccination history: • **Unvaccinated Individuals**: administer a series of two doses (0.5 mL each). The second dose should be administered 3-8 weeks* after the first dose. • **Individuals Previously Vaccinated with Any mRNA COVID-19 Vaccine, NOT including 1 dose any 2024-2025 COVID-19 vaccine**: administer a single 0.5 mL dose at least 8 weeks after receipt of the last previous dose of COVID-19 vaccine. • **Individuals Previously Vaccinated with 1 dose any Novavax:** administer a single 0.5 mL dose 3-8 weeks* after the last dose of Novavax vaccine. • **Individuals Previously Vaccinated with 2 or more doses any Novavax, NOT including 1 dose any 2024-2025 COVID-19 Vaccine:** administer a single 0.5 mL dose at least 8 weeks after the last dose of Novavax vaccine. **Individuals 65 Years of Age and Older Who Are Not Moderately or Severely Immunocompromised**: An additional dose of 2024-2025 COVID-19 vaccine is not currently recommended. **Individuals 12 Years of Age and Older Who Are Moderately or Severely Immunocompromised**:** Administer based on previous COVID-19 vaccination history: • **Unvaccinated Individuals:** administer a series of two doses (0.5 mL each). The second dose should be administered 3 weeks after the first dose.

- **Individuals previously vaccinated with 1 dose any Novavax:** administer a single 0.5 mL dose 3 weeks after the last dose of Novavax vaccine.
- **Individuals previously vaccinated with 2 or more doses any Novavax, NOT including 1 dose any 2024-2025 COVID-19 vaccine**: administer a single 0.5 mL dose at least 8 weeks after the last dose of Novavax vaccine.
- **Individuals previously vaccinated with 3 or more doses any mRNA vaccine, NOT including at least 1 dose any 2024-2025 COVID-19 vaccine:** administer a single 0.5 mL dose at least 8 weeks after the last previous dose of COVID-19 vaccine.

Administration of additional doses is as follows:

People in this age group may receive 1 additional dose of Novavax COVID-19 Vaccine (2024-2025 Formula) at least 2 months following the last recommended 2024-2025 vaccine dose, regardless of the manufacturer of the initial series.

Further additional doses of Novavax COVID-19 Vaccine (2024-2025 Formula) may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. Such instances are beyond the scope of this standing order. Notify the medical provider for an assessment of the individual's clinical circumstances to determine the need for additional doses. Any further additional doses should be administered at least 2 months after the last 2024-2025 COVID-19 vaccine dose.

*An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

**See the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States for the description of moderate and severe immunocompromising conditions and treatments.

COVID-19 Vaccination and Pemivibart

Pemivibart (Pemgarda) is a monoclonal antibody for COVID-19 pre-exposure prophylaxis in people ages 12 years and older who are moderately or severely immunocompromised and unlikely to mount an adequate immune response to COVID-19 vaccination. Healthcare providers should consult the pemivibart EUA fact sheet for the FDA-authorized conditions under which pemivibart should be used.

Pemivibart is not a substitute for COVID-19 vaccination. People who are moderately or severely immunocompromised should receive COVID-19 vaccine according to the recommended schedule. Administration of pemivibart should be deferred for at least 2 weeks after a dose of COVID-19 vaccine.

Assessment Criteria

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Assessment Criteria:	Patients **12** years and older, including those who are moderately or severely immunocompromised, shall be vaccinated with Novavax COVID-19 Vaccine (2024-2025 Formula) based on the conditions/situations of this order (see above).
Plan of Care	
Actions	**Patient Education and Data Collection:** Prior to patients receiving Novavax (2024-2025 Formula), 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. A review of the CDC Screening Checklist for Contraindications. 2. Fact Sheet for Recipients and Caregivers Emergency Use Authorization of Novavax COVID-19 Vaccine Adjuvanted.
	Novavax 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 the Novavax Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula), for Individuals 12 Years of Age and Older. The vaccinator shall be familiar with procedures for preparation and storage & handling of Novavax according to the fact sheet. 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. 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 Novavax. 6. Following the current *CDC Screening Checklist for Contraindications*, instruct patients accordingly or consult with overseeing provider. 7. Individuals under 18 presenting for COVID vaccines under an Emergency Use Authorization must have written consent from the patient's authorized parent or caregiver prior to administration per agency policy and in accordance with NC General Statute. 90-21.13.

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.

Vaccine Product & Preparation:

Novavax, available as a single dose (0.5 mL) pre-filled syringe , is a colorless to slightly yellow, clear to mildly opalescent suspension, free from visible particles.
For intramuscular injection only.

1. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not administer the vaccine if either of these conditions exist.
2. Ensure the pre-filled syringe has not expired. The expiration date is printed on both the box and the individual pre-filled syringes. Novavax is expected to extend the shelf-life of the 2024-2025 product. To confirm the correct expiration date, please utilize the expiry look-up tool. A QR code will be located on the outer vaccine carton that will direct you to the Novavax Expiration Look-up tool. Please scan and look for the most recent changes to expiration dates before administering the vaccine.
3. Administer the 0.5 mL dose intramuscularly .
4. Discard syringe after use.

- People ages 12 years and older not previously vaccinated with any COVID-19 vaccine product who receive a first dose of Novavax COVID-19 Vaccine should complete the 2-dose initial vaccination series with Novavax vaccine, unless one of the following exceptional situations are present: Same vaccine not available; Previous dose unknown, Person would otherwise not complete the vaccination series; Person starts but is unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication. In such instances, a different age-appropriate COVID-19 vaccine may be administered. If a dose of a different product is inadvertently administered, that dose is valid and does not need to be repeated. If more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024-2025 COVID-19 vaccine (i.e. Moderna, Novavax, or Pfizer-BioNTech) may be administered. For further information see guidance on vaccine administration errors and deviations (CDC Interim Clinical Considerations for COVID-19 Vaccine Administration Appendix B).
- When a patient inadvertently receives an incorrect/inappropriate dose of COVID-19 vaccine, review Appendix B. Vaccine administration errors and deviations, and take action as directed.

Timing:

- All recommended doses of Novavax shall be administered as close to the recommended interval as possible. 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.

Administration:

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Route of Administration: Use the chart below to determine appropriate needle gauge and site of intramuscular injection.

Age of Patient	Needle Gauge	Needle Length	Injection Site
Children, 12-18 years	22-25-gauge	*5/8 inch-1 inch	Deltoid muscle
Adults, 19 years and older 1. 130 lbs or less 2. 130-152 lbs 3. Men, 152-200 lbs 4. Women 152-200 lbs 5. Men, 260 lbs or more 6. Women, 200 lbs or more	22-25-gauge • 1 inch • 1 inch • 1-1.5 inches • 1-1.5 inches • 1.5 inches • 1.5 inches	1-1.25 inch	Deltoid muscle

Needle Gauge: Patient's authorized caregiver may self-report the child's weight for needle selection purposes. *If a 5/8-inch needle is used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

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.

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 Simultaneous administration of COVID-19 vaccines with other vaccines

Documentation:

1. Patient or caregiver attestation to severe or moderate immunocompromise should be documented within the patient's electronic health record or other documenting system.
2. **NCIR**: Document vaccine record in NCIR at the time of administration or by close of business day, after vaccine administration.
3. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic health record per agency policy.
4. Provide a signed immunization record, at no charge, to the parent, guardian, or patient each time an immunization is given as specified in G.S. 130A-154 and when needed for schools, childcare facilities, colleges/universities, or wherever immunization records are required.
5. Counsel when and how patient needs to schedule return appointment for subsequent doses of COVID-19 vaccine, if applicable.

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	Novavax COVID-19 Vaccination Observation and Follow Up **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:** Individuals with the following medical histories: • Non-severe, immediate (onset within 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type • Diagnosed non-severe allergy to a component of the COVID-19 vaccine b. **15 minutes**: All other persons **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. **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	1. **Persons receiving immunosuppressive therapies**: Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies. 2. **Persons who receive B-cell-depleting therapies on a continuing basis:** COVID-19 vaccines should be administered approximately 4 weeks before the next scheduled therapy. 3. **Persons who received COVID-19 vaccination outside of the United States:** Everyone ages 6 months and older vaccinated outside the United States should receive at least 1 dose of an updated (2024–2025 Formula) COVID-19 vaccine regardless of past COVID-19 vaccination history (e.g., vaccine type[s], vaccine manufacturer[s], number of doses) unless they received an updated (2023–2024 Formula) COVID-19 vaccine that is FDA-approved or FDA-authorized (i.e., Moderna, Novavax, Pfizer-BioNTech) or listed for emergency use by the World Health Organization (WHO). COVID-19 vaccines that are listed for emergency use by WHO, but are not approved or authorized by FDA, have not been evaluated for efficacy or safety by CDC or ACIP. Recommendations for people who were vaccinated outside the United States, but have not received an updated (2024–2025 Formula) COVID-19 vaccine can be found in Appendix A. People who received COVID-19 vaccine outside the United States.

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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: 1. Vaccine administration errors 2. Serious adverse events 3. Case of myocarditis, cases of pericarditis, and cases of Multisystem Inflammatory Syndrome (MIS) 4. 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.gov or by calling 1-800-822-7967.
Precautions for Use of this Order	1. Persons with a history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine.* 2. Persons with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine.** 3. Patient self-reported moderate to severe acute illness, with or without fever. 4. Persons with a history of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine. 5. Persons with a history of MIS-C or MIS-A. * 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. **Persons with an allergy-related precaution to one COVID-19 vaccine type may receive the alternative COVID-19 vaccine type in the usual vaccination setting. Vaccination with the same COVID-19 vaccine type may be considered on an individual basis; the same vaccine type should be administered in an appropriate setting and under the supervision of a health care provider experienced in the management of severe allergic reactions. An observation period of 30 minutes post-vaccination should be followed. Referral to an allergist-immunologist should also be considered.
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 COVID-19 vaccine* See Table 3. Contraindications and precautions to COVID-19 vaccination: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States *People with a contraindication to one COVID-19 vaccine type may receive the alternative COVID-19 vaccine type in the usual vaccine setting. Consultation with an allergist-immunologist should be considered. See Considerations for people with a history of allergies or allergic reactions.

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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. Patient reports they are an HCT, CAR-T cell, or B-cell-depleting therapy recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 6. Patient has undergone solid organ transplantation or has been diagnosed with a condition that is considered to have an equivalent level of immunocompromise and is requesting additional doses as noted in the condition/situation section of this standing order. 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.

Date Signed: 9/13/24

Approved by: ___Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

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) and Session Law 2023-65, Sec. 9G.7 (to extend authorization through December 31, 2024) 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.