NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
Administration of COMIRNATY (COVID-19 Vaccine, mRNA) in Individuals 12 Years of Age and Older
August 30, 2024

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)

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.

COMIRNATY® (COVID-19 Vaccine, mRNA) 2024-2025 Formula	
Condition/Situation	**Note:** COMIRNATY is the FDA **approved product for use** in persons 12 years and older. **Individuals 12 years of age and older who are not moderately or severely immunocompromised** who present requesting a vaccination will receive the following, regardless of previous COVID-19 vaccine history: • 1 dose 0.3 mL COMIRNATY, administered as an IM injection For individuals previously vaccinated with any COVID-19 vaccine, NOT including 1 dose of any 2024-2025 mRNA vaccine, administer the dose of COMIRNATY at least 8 weeks after the last dose of COVID-19 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. **Moderately to Severely Immunocompromised* Individuals 12 Years and Older** Administer according based on previous COVID-19 vaccination history as noted below: • **Unvaccinated individuals**: Administer three doses 0.3 mL of COMIRNATY. The interval between the first and second dose is a minimum of 3 weeks and the third dose should be given at least 4 weeks after the second dose. • **Individuals who have received 1 dose of any Pfizer-BioNTech COVID-19 Vaccine** : Administer two doses 0.3 mL of COMIRNATY. The first dose should be administered 3 weeks after the last dose and the second dose shall be administered at least 4 weeks after the first. • **Individuals who have received 2 doses of any Pfizer-BioNTech**: Administer a single dose 0.3 mL of COMIRNATY, at least 4 weeks after the last dose of Pfizer-BioNTech COVID-19 Vaccine. • **Individuals who have received ≥3 doses of any mRNA COVID-19 Vaccine, NOT including at least 1 dose any mRNA 2024-2025 vaccine:** Administer a single dose 0.3 mL of COMIRNATY, at least 8 weeks after the last dose of mRNA vaccine. • **Individuals who have received 1 or more doses of Novavax and NOT including 1 dose any 2024-2025 mRNA vaccine:** Administer a single dose 0.3 mL of COMIRNATY, at least 8 weeks after the last COVID-19 vaccine dose.

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COVID-19 vaccination history prior to updated (2024–2025 Formula) vaccine	Updated (2024–2025 Formula) mRNA vaccine	Number of updated (2024–2054 Formula) mRNA doses indicated	Dosage (mL/ug)	Interval between doses
Unvaccinated	COMIRNATY	3	0.3 mL/30 ug	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose any Pfizer-BioNTech	COMIRNATY	2	0.3 mL/30 ug	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	COMIRNATY	1	0.3 mL/30 ug	At least 4 weeks after last dose
3 or more doses any mRNA vaccine, NOT including at least 1 dose any mRNA 2024-2025 vaccine	COMIRNATY	1	0.3 mL/30 ug	At least 8 weeks after last dose
1 or more doses of Novavax , and NOT including 1 dose any 2024-2025 mRNA vaccine	COMIRNATY	1	0.3 mL/30 ug	At least 8 weeks after last dose

Note: Children who transition from age 11 years to age 12 years during the Pfizer-BioNTech initial vaccination series should complete the 3-dose series using the dosage for people ages 12 years and older (0.3 mL/30 ug COMIRNITY) for all doses received on or after turning age 12 years.

Administration of additional doses is as follows:

People in this age group **may** receive 1 additional dose of COMIRNATY COVID-19 Vaccine (2024-2025 Formula) at least 2 months following the last recommended 2024-2025 mRNA vaccine dose.

Further additional doses of COMIRNATY 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. **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.*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.
Assessment Criteria	
Assessment Criteria	Patients 12+ years of age, including those with certain immunocompromising conditions shall be vaccinated with COMIRNATY based on: 1. The conditions/situations of this order (see above).
Plan of Care	
Actions	**Patient Education and Data Collection** Prior to patients receiving the COMIRNATY 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. A review of the CDC Screening Checklist for Contraindications 2. Review of the COVID-19 Vaccine Information Statement (VIS)
	COMIRNATY, 12+ years of age **Administration Procedures:** 1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. 2. Review the COMIRNATY package insert. The vaccinator shall be familiar with procedures for preparation and storage & handling of COMIRNATY according to the package insert. 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 COMIRNATY.
6. Following the current *CDC Screening Checklist for Contraindications* , instruct patients accordingly or consult with overseeing provider.
7. Individuals under 18 years of age presenting for COVID-19 vaccines must have consent from the patient's authorized parent or caregiver prior to administration (Please note: Since COVID-19 disease is no longer a reportable condition, minor's consent law cannot be applied, even for COVID-19 vaccines with full FDA approval).
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:

For intramuscular injection only.

- COMIRNATY glass pre-filled syringes must be stored at 2°C to 8°C (36°F to 46°F) until the expiration date printed on the carton and syringe labels. DO NOT FREEZE. The total time out of refrigeration (at temperatures between 8°C and 25°C (46°F and 77°F)) must not exceed 12 hours. After removing the tip cap and attaching an appropriate needle, the glass pre-filled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours.
- COMIRNATY single dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Thaw each vial before use following the instructions below.

	Thaw in Refrigerator	Thaw at Room Temperature
0.3 mL Single Dose Vial	Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours. Can be stored at room temperature for a total of 12 hours.	Alternatively, thaw at room temperature, up to 25°C (77°F), for 30 minutes. Can be stored at room temperature for a total of 12 hours.

- After thawing, do not refreeze.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

- COMIRNATY is a white to off-white suspension. Do not administer if vaccine is discolored or contains particulate matter.
- For single dose vials:
  - Do not dilute the vaccine.
  - Prior to use, mix by inverting vial gently 10 times. **Do not shake**.
  - Withdraw a single 0.3 mL dose using a sterile needle of the appropriate size for intramuscular injection and syringe.
  - Discard vial and any excess volume.
  - Each vial is single use only.
- For single dose pre-filled syringes:
  - Do not dilute the vaccine.
  - **Do not shake**.
  - Remove tip cap and attach a sterile needle of the appropriate size for intramuscular injection.
- Administer the 0.3 mL dose intramuscularly immediately after preparation. For the prefilled syringe, administer the entire volume to deliver a single 0.3 mL dose.
- Discard syringe after use.
- Individuals who are moderately or severely immunocompromised should receive a 3-dose initial vaccination series using vaccines from the same manufacturer, 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 mRNA product is inadvertently administered, that dose is valid and does not need to be repeated. 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 COMIRNATY 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:

a. **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 2. 130 lbs or less 3. 130-152 lbs 4. Men, 152-200 lbs 5. Women 152-200 lbs 6. Men, 260 lbs or more 7. 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

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. 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:

a. Patient or caregiver attestation to severe or moderate immunocompromise should be documented within the patient's electronic health record or other documenting system.
b. **NCIR**: Document vaccine record in NCIR at the time of administration or by close of business day, after vaccine administration.
c. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic health record per agency policy.
d. 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.
e. Counsel when and how patient needs to schedule return appointment for subsequent doses of COVID-19 vaccine, if applicable.

	COMIRNATY, 12+ years of age: 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	**People who received COVID-19 vaccination outside the United States:** Everyone ages 6 months and older vaccinated outside the U.S. should receive at least 1 dose of 2024-2025 COVID-19 vaccine regardless of past COVID-19 vaccination history (e.g., vaccine type(s), vaccine manufacturer(s), number of doses) unless they received a 2024-2025 COVID-19 vaccine that is FDA-approved or FDA-authorized (i.e., Moderna or Pfizer-BioNTech), or prequalified or listed for emergency use by the World Health Organization (WHO). COVID-19 vaccines that are pre-qualified or 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. Those who are moderately or severely immunocompromised may be recommended to receive more than 1 dose of a 2024-2025 COVID-19 vaccine depending on vaccination history as noted within this standing order. See Appendix A in the Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for more information.

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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. 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: _____ _____ Date Signed: ___8-30-2024_____
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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) 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.