NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for monovalent COMIRNATY/Pfizer mRNA COVID-19 Vaccine Administration in Patients Ages 12 Years and Older
Revised July 25, 2022; Updated August 31, 2022; Revised 1/31/23

Purpose: To meet the goal of administering FDA-approved COMIRNATY and FDA authorized Pfizer BioNTech herein after COMIRNATY/Pfizer vaccines and to protect and save lives in the COVID-19 pandemic by vaccinating persons aged 12 years and older who meet the criteria set-forth by the Food and Drug Administration.

NOTE: On August 31, 2022, the FDA rescinded emergency use authorization of monovalent COMIRNATY/Pfizer mRNA COVID-19 Vaccine Administration in Patients Ages 12 Years and Older as a booster vaccine**.** Eligible patients who request and are eligible for a booster should receive either the Pfizer or Moderna bivalent 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 2022-74, 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.

NOTICE: On January 26, 2023, the FDA revised the EUA for EVUSHELD and rescinded authorization for use in the United States until further notice by the agency.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.

<table>
<tr><th colspan="2">COVID-19 Vaccination</th></tr>
<tr><td>Condition/Situation :
Non-immuno-compromised Patients (Most patients)</td><td>Patients who self-attest to not being moderately to severely immunocompromised shall receive:
➢ <u>Primary Series (2-dose) COMIRNATY/Pfizer:</u>
12 years and older, presenting for COMIRNATY/Pfizer vaccine for the first or second dose of their 2-dose primary series. The second dose shall be given at least 21 days after the first dose and up to 8 weeks per patient request.
Intervals for Doses in Primary Series:
(Table 1)
<table><tr><td>Dose 1 to Dose 2 of COMIRNATY/Pfizer</td><td>3 – 8 weeks*</td></tr></table>*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.</td></tr>
<tr><td>Condition/Situation:
Moderately to Severely Immunocompromised patients</td><td>Patients who attest to being moderately to severely immunocompromised shall receive:
➢ <u>Primary Series (3-dose COMIRNATY/Pfizer):</u>
• 12 years and older, requesting COMIRNATY/Pfizer vaccine for the recommended first, second, or third dose of their 3-dose primary series of mRNA vaccine. (See appropriate interval between doses in table below).
(Table 4)</td></tr>
</table>

	Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People **Dose 1 to Dose 2 of COMIRNATY/Pfizer** — at least 3 weeks* **Dose 2 to Dose 3 of COMIRNATY/Pfizer** — 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. ➢ **Additional (2nd)Dose of COMIRNATY/Pfizer after receiving Janssen vaccine:** • 18 years and older, presenting for COMIRNATY/Pfizer vaccine at least 28 days after receiving their first dose of Janssen COVID-19 vaccine. The additional dose is not a booster dose; these patients should still receive a booster at the appropriate interval. (See table below). **(Table 5)** **Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People** **1st dose of Janssen vaccine to additional dose of COMIRNATY/Pfizer** — At least 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 COMIRNATY, refer to section on "Special Circumstances." *
Condition	In addition to criteria above, the following conditions regarding consent must be met: • Persons 18 years and older, as well as **minors with decisional capacity (1st and 2nd doses only)**, may give effective consent to receive the appropriate dose of COMIRNATY vaccine for prevention of COVID-19 disease and can be vaccinated following verbal consent, under FDA approved status per NCAC minor consent law, NC G.S 90-21.5. • Patients (recipients of vaccine) 12 – 17 years of age presenting for COMIRNATY/Pfizer 3rd dose in primary series due to immunocompromised conditions and whose parent or legal guardian has provided **written** consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status**.** (See table below for clarification).

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- Patients 18 years of age or older who present requesting a third dose of a primary series due to immunocompromised conditions and have legal and decisional capacity to consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status. (See table below for clarification).

Patient Age	Situation	FDA Approved or FDA EUA	Consent required
12 & up	2-dose primary series	Approved	Verbal (minors with decisional capacity)
18 & up	*3rd dose of primary series *Additional dose after Janssen	Emergency Use Authorization	Verbal
16-17	2-dose primary series	Approved	Verbal
16 -17	*3rd dose of primary series	Emergency Use Authorization	Written by parent or legal guardian
12-15	*3rd dose of primary series	Emergency Use Authorization	Written by parent or legal guardian

Assessment Criteria

Assessment Criteria

Patients shall be vaccinated with COMIRNATY/Pfizer COVID-19 Vaccine based on:

1. The conditions/situations of this order (see above).
2. If patient is presenting for first dose of COMIRNATY/Pfizer: ensure there is no history of previous COVID-19 vaccination, regardless of brand.

3. Ensure the minimum interval between doses has been met for the dose patient is to receive. (see appropriate Tables above or CDC Clinical Considerations for further guidance).

4. Moderately and severely immunocompromised people over the age of 12 with written consent from parent or legal guardian, who qualify for a third dose of an mRNA primary series should receive a 3rd dose.

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 three-week interval between dose 1 and dose 2 is the minimum interval between these doses and provides more rapid protection against COVID-19. A three-week interval is recommended for:

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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. An 8-week interval between dose 1 and dose 2 may reduce the risk of myocarditis and may increase peak antibody response/ vaccine effectiveness. An 8-week interval may be optimal for:
i. Males aged 12-39, who do not fall into one of the above categories.
ii. All patients, aged 12-64, who do not fall into one of the above categories.

3. Fact Sheet for Recipients and Caregivers About COMIRNATY (Covid-19 Vaccine, mRNA) for 12 Years of Age and Older.
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 Interim Clinical Considerations for latest vaccine information.
5. V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.

COMIRNATY/Pfizer 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. COMIRNATY/Pfizer COVID-19 vaccine may be supplied in a **PURPLE CAP** formulation or a **GRAY CAP** formulation. The vaccinator shall use the formulation according to local protocol & product availability. The vaccinator shall be familiar with procedures for preparation, storage & handling of the COMIRNATY/Pfizer formulation they are using. Dosage and clinical indications are the same for both formulations.
   a. For the **PURPLE CAP** formulation: review the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for COMIRNATY/Pfizer for 12 Years of Age and Older (PURPLE CAP).
   b. For the **GRAY CAP** formulation: review the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for COMIRNATY/Pfizer for 12 Years of Age and Older (GRAY CAP)
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 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.
    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. Persons 18 years and older, as well as minors with decisional capacity (1st and 2nd doses only), may give effective consent to receive the appropriate dose of COMIRNATY vaccine for prevention of COVID-19 disease and can be vaccinated following verbal consent, under FDA approved status per NCAC minor consent law, NC G.S 90-21.5.
8. A person under age 18 must have written consent from an authorized caregiver to receive Pfizer BioNTech per NC G.S 90-21.5 for:
    a. a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.
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:

10. **Vaccine product:** Ensure the appropriate Pfizer formulation is selected. The COMIRNATY/Pfizer formulation for ages 12 & up shall be selected based on local protocol & product availability. Pfizer COVID-19 vaccine for ages 12 and up (30 µg) will have either:
    a. A **PURPLE CAP** and label. This vaccine must be diluted before use.
    b. A **GRAY CAP** and label. This vaccine should **NOT** be diluted before use.

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older[1,2]	12 years and older[3]	5 through 11 years[4] ("Age 5y to <12y" on label)
Vial Cap Color	Purple	Gray	
Dose	30 mcg	30 mcg	
Dose Volume	0.3 mL	0.3 mL	
Amount of Diluent Needed per Vial*	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)

* Using the formulation for ages 5-11 (10 µg, ORANGE CAP) may result in vaccine administration errors and should not be used in this age group.

11. **Preparation**: Prepare vaccine, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling prepared vaccine.
    a. When using the **PURPLE CAP** formulation, refer to Pfizer COVID-19 Vaccine Preparation and Administration Summary for 12 & Up (PURPLE CAP)
    b. When using the **GRAY CAP** formulation, refer to Pfizer COVID-19 Vaccine Preparation and Administration Summary for 12 & Up (GRAY CAP)
12. **Dosing:**

    a. Administer 0.3 mL (30 µg) COMIRNATY/Pfizer COVID-19 vaccine to patients aged 12 and up. The dose is the same regardless of whether the patient is receiving a primary series dose, or an additional dose.
    b. In patients who have initiated an mRNA COVID-19 vaccine (COMIRNATY/Pfizer or Moderna/SPIKEVAX) primary series: patients shall 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.
    c. Patients shall be vaccinated with the age-appropriate Pfizer product/dose based on the age they are on the day they present for vaccination.
    d. Children who turned from age 11 to age 12 between their first and second doses do not need to repeat a second dose if the 10 µg (ORANGE cap) formulation is given for the second dose.

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

13. **Timing:**
    a. All recommended doses of COMIRNATY/Pfizer 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. (See interval tables above)
    b. See Interim Clinical Considerations, Appendix E for information on COVID-19 vaccine errors and administration deviations.
14. **Administration:**
    a. **Route of Administration:** Administer COMIRNATY/Pfizer 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.
    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 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	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	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 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

15. **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.

16. **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.
17. **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 second, third, or booster dose of COVID-19 vaccine, if applicable.

COMIRNATY/Pfizer COVID-19 Vaccination Observation and Follow-Up

1. **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:**
        - Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine
        - 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 or Moderna/SPIKEVAX) should be observed for 30 minutes following vaccination.
        - 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 to respond to severe allergic reactions and 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 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. *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 primary series) **should not** receive a single booster dose of Pfizer-BioNTech COVID-19 Vaccine (ages 12 years and older) or Moderna COVID-19 Vaccine (ages 18 years and older). If clinical trial participants have questions about whether they should receive a 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.
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

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	2. Serious adverse events 3. Cases of Multisystem Inflammatory Syndrome 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.govexternal icon or by calling 1-800-822-7967.
Precautions for Use of this Order	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. 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 • Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. See Interim Clinical Considerations, Appendix E: Triage of people with history of allergies or allergic reactions
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.

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	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 vax 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: __8-31-22_____

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

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