



NC State Health Director’s Statewide Standing Order for COMIRNATY/Pfizer mRNA COVID-19 Vaccine Administration in Patients Age 12 Years and Older Revised March 31, 2022

Purpose: To meet the goal of administering FDA-approved (COMIRNATY), FDA-Emergency Use Authorization (Pfizer BioNTech) herein-after Pfizer/COMIRNATY 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.

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 Executive Order 245, or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively “vaccinators”) to administer FDA approved COVID-19 Vaccines and/or COVID -19 vaccines authorized by the FDA through an Emergency Use Authorization (EUA) per conditions of this order.

Table with 2 columns: Condition/Situation and COVID-19 Vaccination. The table details vaccination protocols for non-immunocompromised patients, including primary series and booster dose scenarios.



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**Heterologous use of vaccine product and intervals for primary dose to 1st booster dose:  
(Table 2)**

Primary Series Vaccine	Age for vaccine booster	Interval between final primary dose and booster dose	COVID-19 product that may be given as a 1 <sup>st</sup> booster dose
<b>Pfizer/COMIRNATY</b>	≥ 18 years*	≥ 5 months	Pfizer Moderna Janssen
<b>Pfizer/COMIRNATY</b>	12-17 years	≥ 5 months	This age group only eligible for Pfizer
<b>Moderna/SPIKEVAX</b>	≥ 18 years*	≥ 5 months	Pfizer Moderna Janssen
<b>Janssen</b>	≥ 18 years*	≥ 2 months	Pfizer Moderna Janssen

\*Regarding booster doses: patients 18 years of age and older can receive any brand of COVID-19 vaccine for their booster shot, upon their request.

\*\*For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting booster dose of COMIRNATY/Pfizer, refer to section on “Special Circumstances.”

- **2<sup>nd</sup> Booster Dose (Pfizer/COMIRNATY) Booster Dose scenarios:**
- **Pfizer/COMIRNATY COVID-19 1<sup>st</sup> Booster Vaccination:**  
50 years of age and older, who present requesting a 2<sup>nd</sup> booster dose at least 4 months after 1<sup>st</sup> booster dose with Pfizer/COMIRNATY.
- **Moderna/ SPIKEVAX COVID-19 1st Booster Vaccination:**  
50 years of age and older, who present requesting a 2<sup>nd</sup> booster dose at least 4 months after 1<sup>st</sup> booster dose with Moderna/SPIKEVAX.
- **Janssen COVID-19 1<sup>st</sup> Booster Vaccination:**
  - \*\*\*18-49 years, who received Janssen COVID-19 vaccine as **both** their primary series and first booster dose who present requesting a 2<sup>nd</sup> booster at least 4 months after their first booster dose
  - \*\*\*50 years and older, who received a mRNA vaccine as primary series and a Janssen as 1<sup>st</sup> booster, present requesting a 2<sup>nd</sup> booster dose at least 4 months after 1<sup>st</sup> booster dose of Janssen



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	<p><b>Heterologous use of vaccine product and interval from 1st booster dose to 2<sup>nd</sup> booster dose: (Table 3)</b></p> <table border="1"> <thead> <tr> <th>1<sup>st</sup> Booster Dose</th> <th>Age for 2<sup>nd</sup> Booster</th> <th>Interval between 1<sup>st</sup> and 2<sup>nd</sup> Booster dose</th> <th>COVID-19 product that may be given for 2<sup>nd</sup> booster dose</th> </tr> </thead> <tbody> <tr> <td><b>Pfizer/COMIRNATY</b></td> <td>≥ 50 years*</td> <td>≥ 4months</td> <td>Pfizer Moderna</td> </tr> <tr> <td><b>Moderna/SPIKEVAX</b></td> <td>≥ 50 years*</td> <td>≥ 4 months</td> <td>Pfizer Moderna</td> </tr> <tr> <td><b>Janssen</b></td> <td>18-49***</td> <td>≥ 4 months</td> <td>Pfizer Moderna</td> </tr> <tr> <td><b>Janssen</b></td> <td>≥ 50 years*</td> <td>≥ 4 months</td> <td>Pfizer Moderna</td> </tr> </tbody> </table> <p>*Regarding booster doses: Upon their request patients 50 years of age and older can receive any brand of COVID-19 vaccine for their 2<sup>nd</sup> booster shot.  **For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting 2<sup>nd</sup> booster dose of Moderna/SPIKEVAX, refer to section on “Special Circumstances.”  ***See Janssen 2<sup>nd</sup> Booster criteria above.</p>	1 <sup>st</sup> Booster Dose	Age for 2 <sup>nd</sup> Booster	Interval between 1 <sup>st</sup> and 2 <sup>nd</sup> Booster dose	COVID-19 product that may be given for 2 <sup>nd</sup> booster dose	<b>Pfizer/COMIRNATY</b>	≥ 50 years*	≥ 4months	Pfizer Moderna	<b>Moderna/SPIKEVAX</b>	≥ 50 years*	≥ 4 months	Pfizer Moderna	<b>Janssen</b>	18-49***	≥ 4 months	Pfizer Moderna	<b>Janssen</b>	≥ 50 years*	≥ 4 months	Pfizer Moderna
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<p><b>Condition/Situation:</b> <b>Moderately to Severely Immunocompromised patients</b></p>	<p>Patients who self-attest to being <a href="#">moderately to severely immunocompromised</a> shall receive:</p> <ul style="list-style-type: none"> <li>➤ <b>Primary Series (3-dose Pfizer/COMIRNATY):</b> <ul style="list-style-type: none"> <li>• 12 years and older, requesting Pfizer/COMIRNATY 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).</li> </ul> </li> </ul> <p><b>(Table 4)</b></p> <table border="1"> <thead> <tr> <th colspan="2"><b>Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People</b></th> </tr> </thead> <tbody> <tr> <td><b>Dose 1 to Dose 2 of COMIRNATY/Pfizer</b></td> <td>3 weeks*</td> </tr> <tr> <td><b>Dose 2 to Dose 3 of COMIRNATY/Pfizer</b></td> <td>4 weeks</td> </tr> </tbody> </table> <p>*See “Patient Education and Data Collection” and <a href="#">considerations for intervals for mRNA COVID-19 vaccine primary series</a> for information on counselling patients on the interval between dose 1 and dose 2.</p>	<b>Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People</b>		<b>Dose 1 to Dose 2 of COMIRNATY/Pfizer</b>	3 weeks*	<b>Dose 2 to Dose 3 of COMIRNATY/Pfizer</b>	4 weeks														
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- **Additional (2<sup>nd</sup>) Dose of Pfizer/COMIRNATY after receiving Janssen vaccine:**
  - 18 years and older, presenting for Pfizer/COMIRNATY 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	
<b>1<sup>st</sup> dose of Janssen vaccine to additional dose of COMIRNATY/Pfizer</b>	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/Pfizer, refer to section on “Special Circumstances.”

- **1<sup>st</sup> Booster Dose )Pfizer/COMIRNATY) scenarios (based on primary series):**
  - Pfizer/COMIRNATY COVID-19 Vaccination primary series:  
12 years of age and older, requesting a booster dose at least 3 months after completion of their primary series with Pfizer/COMIRNATY.
  - Moderna/SPIKEVAX COVID-19 Vaccination primary series:  
18 years of age and older, requesting a booster dose at least 3 months after completion of their primary series with Moderna/SPIKEVAX.
  - Janssen COVID-19 Vaccination primary series & additional dose of mRNA vaccine:  
18 years and older, who received their first dose of COVID-19 vaccination with Janssen, followed by an additional dose of mRNA vaccine (see criteria above). The patient should have received their additional dose of mRNA vaccine at least 2 months ago.

**Heterologous use of vaccine product as noted in table below:(Table 6)**

Intervals for Booster Doses: patients who are Moderately to Severely Immunocompromised			
Primary Series Vaccine	Age for vaccine booster	Interval between final primary dose and booster dose	COVID-19 product that may be given as a 1 <sup>st</sup> booster dose
Pfizer/COMIRNATY	≥ 18 years	≥ 3 months	Pfizer Moderna Janssen



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<b>Pfizer/COMIRNATY</b>	12-17 years	≥ 3 months	<b>This age group only eligible for Pfizer</b>
<b>Moderna/SPIKEVAX</b>	≥ 18 years	≥ 3 months	Pfizer Moderna Janssen
<b>Janssen *** (1 dose, followed by additional dose of mRNA vaccine)</b>	≥ 18 years	≥ 2 months after additional dose of mRNA vaccine	Pfizer Moderna Janssen

\*Regarding booster doses: Upon their request, patients 18 years of age and older can receive any brand of COVID-19 vaccine for their booster shot.  
 \*\*For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting booster dose of COMIRNATY/Pfizer, refer to section on “Special Circumstances.”  
 \*\*\*For patients who received an additional Janssen dose following their primary Janssen dose or who received 50 mcg dose of Moderna as their 2<sup>nd</sup> dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 mcg )as the 3<sup>rd</sup> dose at least 2 months after dose 2. For further guidance see CDC Interim Clinical Considerations, Appendix D.

- **2<sup>nd</sup> Booster Dose Pfizer/COMIRNATY scenarios:**
- **Pfizer/COMIRNATY COVID-19 1<sup>st</sup> Booster Vaccination:**  
12 years of age and older, requesting a 2<sup>nd</sup> booster dose at least 4 months after 1<sup>st</sup> booster dose with Pfizer/COMIRNATY.
  - **Moderna/SPIKEVAX COVID-19 1<sup>st</sup> Booster Vaccination:**  
18 years of age and older, requesting a 2<sup>nd</sup> booster dose at least 4 months after 1<sup>st</sup> booster dose with Moderna/SPIKEVAX.
  - **Janssen COVID-19 1<sup>st</sup> Booster Vaccination:**  
18 years and older, who received their first dose of COVID-19 vaccination with Janssen, followed by an additional dose of mRNA vaccine (see criteria above). The patient should have received their additional dose of mRNA vaccine at least 4 months ago.

**Heterologous use of vaccine product and interval between booster doses: (Table 7)**

<b>Primary Series Vaccine</b>	<b>Age for vaccine booster</b>	<b>Interval between 1<sup>st</sup> and 2<sup>nd</sup> booster dose</b>	<b>COVID-19 product that may be given as a 2<sup>nd</sup> booster dose</b>
<b>Pfizer/COMIRNATY</b>	≥ 18 years*	≥ 4 months	Pfizer Moderna



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<b>Condition</b>	<p>*Regarding booster doses: Upon their request, patients 18 years of age and older can receive either brand of COVID-19 vaccine for their 2nd booster shot.</p> <p>**For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting booster dose of COMIRNATY/Pfizer, refer to section on “Special Circumstances.”</p> <p>*** For further guidance see <a href="#">CDC Interim Clinical Considerations, Appendix D.</a></p> <p>In addition to criteria above, the following conditions regarding consent must be met:</p> <ul style="list-style-type: none"> <li>• Patients (recipients of vaccine) 16-years of age or older who present requesting COMIRNATY/Pfizer vaccine for the first 2 dose series and have legal and decisional capacity to consent to the vaccine will be vaccinated following verbal consent, under FDA approved status per NCAC <a href="#">minor consent law</a> , <a href="#">NC G.S 90-21.13</a> and <a href="#">Session Law 2021-110. (Section 9, a1)</a>.</li> <li>• Patients (recipients of vaccine) 12 – 15 years of age presenting for COMIRNATY/Pfizer for the first 2 dose series, patients (recipients of vaccine) 12 – 17 years of age presenting for COMIRNATY/Pfizer for a 3<sup>rd</sup> dose in primary series due to immunocompromised conditions, and patients 12-17 years of age presenting for a booster dose of Pfizer/COMIRNATY and whose parent or legal guardian has provided <b>written</b> consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status. (See table below for clarification).</li> <li>• Patients 18 years of age or older who present requesting a third dose of a primary series due to immunocompromised conditions or a booster dose based on the criteria above 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).</li> </ul> <table border="1"> <thead> <tr> <th>Patient Age</th> <th>Situation</th> <th>FDA Approved or FDA EUA</th> <th>Consent required</th> </tr> </thead> <tbody> <tr> <td><b>18 &amp; up</b></td> <td>2-dose primary series</td> <td>Approved</td> <td>Verbal</td> </tr> <tr> <td><b>18 &amp; up</b></td> <td>*3<sup>rd</sup> dose of primary series *Additional dose after Janssen *Booster dose 1 and 2</td> <td>Emergency Use Authorization</td> <td>Verbal</td> </tr> <tr> <td><b>16-17</b></td> <td>2-dose primary series</td> <td>Approved</td> <td>Verbal</td> </tr> <tr> <td><b>16 -17</b></td> <td>*3<sup>rd</sup> dose of primary series *Booster dose 1 and 2</td> <td>Emergency Use Authorization</td> <td>Written</td> </tr> <tr> <td><b>12-15</b></td> <td>*2-dose primary series</td> <td>Emergency Use Authorization</td> <td>Written</td> </tr> </tbody> </table>	Patient Age	Situation	FDA Approved or FDA EUA	Consent required	<b>18 &amp; up</b>	2-dose primary series	Approved	Verbal	<b>18 &amp; up</b>	*3 <sup>rd</sup> dose of primary series *Additional dose after Janssen *Booster dose 1 and 2	Emergency Use Authorization	Verbal	<b>16-17</b>	2-dose primary series	Approved	Verbal	<b>16 -17</b>	*3 <sup>rd</sup> dose of primary series *Booster dose 1 and 2	Emergency Use Authorization	Written	<b>12-15</b>	*2-dose primary series	Emergency Use Authorization	Written
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	*3 <sup>rd</sup> dose of primary series *Booster dose 1 and 2
<b>Assessment Criteria</b>	
<b>Assessment Criteria</b>	<p>Patients shall be vaccinated with COMIRNATY/Pfizer COVID-19 Vaccine based on:</p> <ol style="list-style-type: none"> <li>1. The conditions/situations of this order (see above).</li> <li>2. If patient is presenting for first dose of Pfizer/COMIRNATY: ensure there is no history of previous COVID-19 vaccination, regardless of brand.</li> <li>1. <b>If patient is presenting for second, third, or a 1<sup>st</sup> or 2<sup>nd</sup> booster dose of COMIRNATY/Pfizer:</b> ensure that the minimum interval between doses has been met. (see appropriate Tables above or <a href="#">CDC Clinical Considerations</a> for further guidance).</li> <li>3. Moderately and severely immunocompromised people over the age of 12 who qualify for a third dose of an mRNA primary series may also receive up to 2 mRNA COVID-19 booster doses (as appropriate based on conditions and criteria noted above). These patients <b>may receive a total of five (5) COVID-19 vaccine doses.</b></li> <li>4. Patients aged 50 or older who are not immunocompromised may receive a 2<sup>nd</sup> mRNA COVID-19 booster dose (as appropriate based on conditions noted above). These patients <b>may receive a total of four (4) COVID-19 vaccine doses.</b></li> </ol>
<b>Plan of Care</b>	
<b>Actions</b>	<p><b>Patient Education and Data Collection</b></p> <p>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:</p> <ol style="list-style-type: none"> <li>1. Review <a href="#">CDC Pre-Vaccination Checklist for COVID-19 Vaccine</a>.</li> <li>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.             <ol style="list-style-type: none"> <li>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:                 <ol style="list-style-type: none"> <li>i. People who self-attest to being moderately to severely immunocompromised</li> <li>ii. Adults aged 65 and older</li> <li>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 <a href="#">CDC’S list of People with Certain Medical Conditions</a></li> </ol> </li> <li>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:                 <ol style="list-style-type: none"> <li>i. Males aged 12-39, who do not fall into one of the above categories.</li> <li>ii. All patients, aged 12-64, who do not fall into one of the above categories.</li> </ol> </li> </ol> </li> </ol>



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3. [Fact Sheet for Recipients and Caregivers About COMIRNATY \(Covid-19 Vaccine, mRNA\) and Pfizer-BioNTech COVID-19 Vaccine 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.

**Pfizer/COMIRNATY 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. Pfizer/COMIRNATY 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 Pfizer/COMIRNATY 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.





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7. Consent must be obtained from the patient or the patient's legally authorized representative prior to vaccine administration per conditions of this order, agency policy and in accordance with [NC General Statute 90-21.13](#) and [Minor Consent Law](#) and [Session Law 2021-110. \(Section 9, a1\)](#)
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:**

9. **Vaccine product:** Ensure the appropriate Pfizer formulation is selected. The Pfizer/COMIRNATY 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 <sup>1,2</sup>	12 years and older <sup>3</sup>	5 through 11 years* ("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 <sup>1</sup>	1.8 mL	NO DILUTION	0.3 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.

10. **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 \(GRAY CAP\)](#)

11. **Dosing:**



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- a. Administer 0.3 mL (30 µg) Pfizer/COMIRNATY 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, additional dose, or 1<sup>st</sup> or 2<sup>nd</sup> booster dose.
- b. In patients who have initiated an mRNA COVID-19 vaccine (Pfizer/COMIRNATY 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 and deviations, and take action as directed.

**12. 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. **Timing (interval) of 1st booster dose is determined by what brand of COVID-19 Vaccine was administered for Primary Series (see [Table 3](#) above). Timing (interval) of 2<sup>nd</sup> booster dose is same regardless of primary or 1<sup>st</sup> booster dose (see [Table 7](#) above).**
- c. See [Interim Clinical Considerations, Appendix C](#) for information on COVID-19 vaccine errors and administration deviations.

**13. Administration:**

- a. **Route of Administration:** Administer Pfizer/COMIRNATY 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:



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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**).

14. **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](#).
15. **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.
16. **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.



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	<p><b>Pfizer/COMIRNATY COVID-19 Vaccination Observation and Follow-Up</b></p> <ol style="list-style-type: none"> <li>1. <b>Post-vaccination Observation:</b> 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 <a href="#">Centers for Disease Control and Prevention guidelines</a> for the following time periods:             <ol style="list-style-type: none"> <li>a. <b>30 minutes:</b> <ul style="list-style-type: none"> <li>• Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine</li> <li>• Persons with a history of anaphylaxis due to any cause</li> <li>• 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/SPIKEVAX) should be observed for 30 minutes following vaccination.</li> <li>• Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy</li> </ul> </li> <li>b. <b>15 minutes:</b> All other persons</li> </ol> </li> <li>2. <b>Anaphylaxis Management:</b> 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 <a href="#">severe allergic reactions and anaphylaxis</a>.</li> <li>3. <b>Syncope:</b> 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.</li> </ol>
<p><b>Special Circumstances</b></p>	<p><b>People who received COVID-19 vaccination outside the United States:</b> 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 E (<a href="#">People who received COVID-19 vaccine outside the United States</a>) and take action/ consult with medical provider as directed.</p> <p><b>Participants in clinical trials within or outside the United States</b> 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.</p> <ul style="list-style-type: none"> <li>• Moderately or severely immunocompromised clinical trial participants should receive an additional dose of Pfizer-BioNTech COVID-19 Vaccine (ages 12 years</li> </ul>



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	<p>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.</p> <ul style="list-style-type: none"> <li>Clinical trial participants (including moderately or severely immunocompromised people who received a 3-dose primary series) <b>should</b> 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), unless they have received or plan to receive a booster dose through a clinical trial.</li> </ul> <p>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.</p>
<b>Follow-up</b>	<p>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:</p> <ol style="list-style-type: none"> <li>Vaccine administration errors</li> <li>Serious adverse events</li> <li>Cases of Multisystem Inflammatory Syndrome</li> <li>Cases of COVID-19 that result in hospitalization or death</li> </ol> <p>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 <a href="https://vaers.hhs.gov/external/icon">https://vaers.hhs.gov/external/icon</a> or by calling 1-800-822-7967.</p>
<b>Precautions for Use of this Order</b>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>Patient self-reported moderate to severe acute illness.</li> <li>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.</li> </ol>



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Table with 2 columns: Criteria/Contraindications and Details. Rows include 'Contraindications for Use of this Order' and 'Criteria or Circumstances for Notifying Medical Provider'.

Handwritten signature of Elizabeth Cuervo Tilson

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

Date Signed: 3-31-22

This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. This order will expire upon rescission off the State of Emergency Executive Order Number 116. Legal Authority: Executive Order 245.