



**NC State Health Director’s Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
Revised April 09 2021**

Purpose: To meet the goal of administering FDA-authorized COVID-19 vaccines, and to protect and save lives in the COVID-19 pandemic by vaccinating persons who meet the criteria authorized by the Food and Drug Administration and recommended 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 [Executive Order 193](#), 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 through an Emergency Use Authorization (EUA) and per conditions of this order.

COVID-19 Vaccination	
Condition or Situation	Patients (recipients of vaccine), 18 years of age and older, present requesting and consent to Janssen COVID-19 Vaccine and have legal and decisional capacity to consent to the vaccine.
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Janssen COVID-19 Vaccine based on: <ol style="list-style-type: none"> 1. the conditions of this order. 2. no history of complete COVID-19 vaccination, regardless of brand.
Plan of Care	
Actions	<ol style="list-style-type: none"> 1. 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: <ol style="list-style-type: none"> a. CDC Pre-Vaccination Checklist for COVID-19 Vaccine at: https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf b. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and older. For the most current version see https://www.janssencovid19vaccine.com c. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html 2. COVID-19 Vaccination Administration Procedures <ol style="list-style-type: none"> 1. Review Interim Clinical Considerations for Use of COVID-19 vaccines. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html



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	<ol style="list-style-type: none">2. 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 COVID-19 vaccine.3. 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 precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.4. Review Precautions, Contraindications, and Criteria or Circumstances for Notifying Medical Provider sections of this standing order before administering the COVID-19 vaccine.5. Instruct patients with a history of allergic reactions, including severe allergic reactions, NOT related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), that these are NOT contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. Inform these patients that there are unknown risks of developing a severe allergic reaction and they will be observed for any signs of allergic reaction after vaccination. Inform patients who have a history of anaphylaxis they will be observed for 30 minutes and other people for 15 minutes.6. Instruct patients that persons with a contraindication to one type of a COVID-19 vaccine (e.g., mRNA-Pfizer or Moderna) have a precaution to the other (e.g., viral vector-Janssen/Johnson and Johnson) because of potential cross-reactive hypersensitivity. Consultation with an allergist 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. If a patient has this precaution, consult the supervising medical provider.7. Review the patient-completed CDC Pre-Vaccination Checklist for COVID-19 Vaccine at: https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf8. Instruct patients who present under the following conditions:<ol style="list-style-type: none">1. If a patient indicates they are feeling sick, ask them if they have a moderate to severe illness. If patient says yes, consult the supervising medical provider.2. Instruct patients with bleeding disorders or who take blood thinners.
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	<ul style="list-style-type: none">a. they may have increased bleeding after intramuscular injection, andb. to call their primary care provider or seek other medical care if the injection site starts bleeding after leaving the vaccination clinic and cannot be stopped by applying pressure. <ul style="list-style-type: none">3. Instruct patients who have received passive antibody therapy as a treatment for COVID-19 that COVID-19 vaccination will be deferred for at least 90 days since their last treatment as a precautionary measure to avoid interference of the antibody treatment with vaccine-induced immune responses.4. Instruct patients who have had another vaccine in the last 14 days that the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine. Patients will need to schedule the vaccine appointment to allow for the 14-day interval between vaccines. A shorter interval may be followed after consultation and order by the supervising medical provider to avoid barriers and delay of vaccination.5. Instruct patients with known current symptomatic SARS-CoV-2 infection their vaccine will be deferred until the patient has recovered from the acute illness and criteria have been met for them to discontinue isolation.6. Instruct patients who are immunocompromised regarding unknown vaccine safety and effectiveness, that the vaccine might be less effective than in someone who is immunocompetent, potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19.7. Instruct patients who are pregnant or lactating (breastfeeding) that these conditions are not contraindications to COVID-19 vaccine and may choose to get vaccinated. Educate the patient that there are limited data currently available on the safety of COVID-19 vaccines in pregnant women, but studies and results are expected soon. Data demonstrate that while the absolute risk is low, pregnant women with COVID-19 have an increased risk of severe illness. Also, educate patients that there are no data available for lactating women on vaccines' effects on lactating women.9. Consent must be obtained from the patient or the patient's legally authorized representative prior to vaccine administration per agency policy and in accordance with G.S. 90-21.13. Consent may be obtained verbally.
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3. 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.
4. Vaccine Preparation and Administration:
 1. **Preparation**: Follow manufacturer’s guidance for thawing, storing/handling and mixing vaccine. Refer to: <https://www.fda.gov/media/146304/download>
 2. **Janssen COVID-19 Vaccine Administration**: Administer 0.5 mL Janssen COVID-19 Vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 18 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used.
 3. **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 Injection Site*	Needle Gauge	Needle Length
Female or male fewer than 130 lbs.	22–25	5/8 ** –1"
Female or male 130–152 lbs.	22–25	1"
Female 152–200 lbs.	22–25	1-11/2"
Male 153–260 lbs.	22–25	1-11/2"
Female 200+ lbs.	22–25	1 1/2"
Male 260+ lbs.	22–25	1 1/2"

- * 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**).
4. **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.
 5. **Post-vaccination Observation**: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patient’s post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>) for the following time periods:



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	<p>a. 30 minutes:</p> <ol style="list-style-type: none">1. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy2. Persons with a history of anaphylaxis due to any cause3. Persons with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen/Johnson and Johnson viral vector vaccine should be observed for 30 minutes following Janssen vaccination). <p>b. 15 minutes: All other persons</p> <ol style="list-style-type: none">6. 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. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html7. Coadministration with other vaccines: COVID-19 vaccines shall not be administered at the same time as other vaccines. Separate COVID-19 vaccines from other vaccines by 14 days before or after the administration of COVID-19 vaccine. A shorter interval may be followed after consultation and order by the supervising medical provider to avoid barriers and delay of vaccination.8. If first dose of mRNA COVID-19 vaccine was received but the patient is unable to complete series with same or different mRNA vaccine (e.g., contraindication) single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose. (See precaution section if the patient has a contraindication for a different COVID-19 vaccine.) Patient is considered to have received valid, single-dose Janssen vaccination, not a mixed vaccination series (mRNA/viral vector).9. CVMS: Document vaccine record in CVMS within 24 hours after vaccine administration per system guidelines found at: https://covid19.ncdhhs.gov/vaccines/providers/covid-19-vaccine-management-system-cvms. 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.10. Electronic Medical Record: If necessary, for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.11. Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product
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	name/manufacturer, lot number, date of vaccination, name/location of vaccinator and clinic site.
Follow-up	<p>1. Vaccinators administering COVID-19 vaccine must report the following information associated with the administration of the vaccine in accordance with the manufacturer’s fact sheets for healthcare providers administering Janssen vaccine: https://www.fda.gov/media/146304/download</p> <ul style="list-style-type: none"> • Vaccine administration errors, whether associated with an adverse event or not. • Serious adverse events (irrespective of attribution to vaccination) • Cases of Multisystem Inflammatory Syndrome in adults • Cases of COVID-19 that result in hospitalization or death <p>Complete and submit reports to VAERS online at: https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967. The reports should include the words “Janssen COVID-19 Vaccine EUA” in the report’s description section. Vaccinators are required to follow the instructions in the letter issued by the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for emergency use of COVID-19 for Janssen COVID-19 Vaccine at: https://www.fda.gov/media/146303/download</p>
Precautions for Use of this Order	<ol style="list-style-type: none"> 1. History of an immediate allergic reaction to any other vaccine or injectable therapies not related to a component of COVID-19 vaccines. 2. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., mRNA-Pfizer or Moderna) have a precaution to the other (e.g., viral vector-Janssen/Johnson and Johnson) because of potential cross-reactive hypersensitivity. Consultation with an allergist 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.
Contraindications for Use of this Order	<ol style="list-style-type: none"> 1. Do not administer the Janssen COVID-19 Vaccine to individuals with a history of: <ul style="list-style-type: none"> • 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. <p><i>See Appendix C: Interim Clinical Considerations for use of Covid-19 Vaccines Currently Authorized in the United States:</i> https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</p>



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Criteria or Circumstances for Notifying Medical Provider	<ol style="list-style-type: none">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. 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.
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Approved by: _____

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

Date Signed: 4-09-21_____

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 193](#).