NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
Revised November 19th, 2021

Purpose: To meet the goal of administering FDA- Emergency Use Authorization Janssen COVID-19 vaccine, 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 236 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 have legal capacity to consent to single dose Primary Series, or single Booster dose of **Janssen COVID-19 Vaccine,** will be vaccinated under the FDA-EUA status**.** Patients should be vaccinated under the following conditions: **Primary Vaccination**: • 18 years of age and older, who present requesting and consent to single dose of primary vaccination with Janssen COVID-19 vaccine. **Janssen Booster Dose Situations** Persons who completed series of COVID-19 vaccination with Janssen: Anyone 18 years of age and older, who present requesting and consent to a booster dose of Janssen COVID-19 vaccine at least two months after their primary series Persons who completed series of COVID-19 Vaccination with Moderna or Pfizer/COMIRNATY: • Anyone 18 years of age and older, who present requesting a booster dose at least 6 months after completion of their primary series. • 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.
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Janssen COVID-19 Vaccine based on: 1. the conditions of this order 2. If patient is presenting for first dose of Janssen: ensure there is no history of previous COVID-19 vaccination, regardless of brand. If patient is presenting for booster dose of Janssen: ensure that the minimum interval between doses has been met. **Timing (interval) of booster dose is determined by what brand of COVID-19 Vaccine was administered for Primary Series**. See the below chart for minimum intervals between booster doses:

NC State Health Director's Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
Revised November 19th, 2021

	<table><tr><td>Single Dose of Janssen to Booster Dose of Janssen</td><td>** + End of 2 OR 3-dose mRNA series (Moderna or Pfizer/ COMIRNATY) to booster dose of Janssen</td></tr><tr><td>2 months</td><td>6 months</td></tr></table> **see the section above on booster doses to determine if a booster dose is appropriate after completion of the Moderna, Pfizer/COMIRNATY or Janssen primary series. + Moderately and severely immunocompromised people aged ≥18 years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose. In such situations, people who are moderately and severely immunocompromised **may receive a total of four COVID-19 vaccine doses**.
Plan of Care	
Actions	**Patient Education and Data Collection:** 1. 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: a. CDC Pre-Vaccination Checklist for COVID-19 Vaccine b. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine c. Women aged <50 should be made aware of the rare risk of thrombosis with thrombocytopenia syndrome (TTS) among Janssen COVID-19 recipients and the availability of other FDA-authorized and FDA-approved COVID-19 vaccines. d. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.
	Janssen COVID-19 Vaccination Administration Procedures 1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. 2. Review the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for Janssen (Johnson & Johnson). 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 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 *Precautions*,*Special Circumstances*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine.
6. Follow the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines Information for Healthcare Providers*, and instruct patients accordingly or consult with overseeing provider.
7. 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.
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.
9. **Vaccine Preparation and Administration**:
    a. **Preparation**: Follow manufacturer's guidance for thawing, storing/handling and mixing vaccine. Refer to: https://www.fda.gov/media/146304/download
    b. **Vaccine Product and Dosing**:
        i. **Primary Vaccination (Single Dose): Administer 0.5 mL Janssen COVID-19** Vaccine. This vaccination is administered as a single dose primary vaccination.
        ii. **Booster dose of Janssen: Administer 0.5 mL Janssen COVID-19 Vaccine**. *Single booster dose of Janssen COVID-19 vaccine is recommended to all patients, age 18 years of age and older, who received their first Janssen COVID-19 vaccine at least 2 months ago. **Single booster dose of the Janssen COVID-19 vaccine may be administered as a heterologous booster dose following completion of primary vaccination series with Pfizer/COMIRNATY or Moderna at least six months ago. (See above chart in Assessment Criteria for clarification of intervals)
        iii. + Moderately and severely immunocompromised people aged ≥18 years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose. In such situations, people who are moderately and severely immunocompromised may receive a total of four COVID-19 vaccine doses.
    c. **Route of Administration:** Administer Janssen vaccine via 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.
    d. **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**).

e. **Multiple vaccinations:** If multiple vaccinations are administered at a single visit, administer each injection in a different injection site following guidance in the CDC Interim Clinical Considerations at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

f. **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.

10. **Timing:** *Single booster dose of Janssen COVID-19 vaccine is recommended to all patients, age 18 years of age and older, who received their first Janssen COVID-19 vaccine at least 2 months ago. **Single booster dose of the Janssen COVID-19 vaccine may be administered as a heterologous booster dose following completion of primary vaccination series with Pfizer/COMIRNATY or Moderna at least six months ago. (See above chart in Assessment Criteria for clarification of intervals). There is a 4-day grace period for booster doses; booster doses administer 4 days before the required interval are considered valid and do not need to be repeated.
11. **Documentation:**
    a. **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.
    b. **Electronic Medical Record**: If necessary, for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.

	c. 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.
	Janssen 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 (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) for the following time periods: a. **30 minutes**: i. Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine ii. Persons with a history of anaphylaxis due to any cause iii. 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). iv. 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. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html 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	1. **People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine:** a. If they received all of the recommended doses of a single dose or 2-dose primary COVID-19 vaccine series, they are considered fully vaccinated. People who are moderately or severely immunocompromised and were vaccinated with a 2-dose mRNA COVID-19 vaccine primary series should receive an additional primary dose as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people. People vaccinated with an FDA-approved or FDA-authorized COVID-19 vaccine

outside the United States should also follow guidance for booster doses as detailed in Considerations for use of a COVID-19 booster dose.

b. If they received the first dose of a 2-dose mRNA COVID-19 vaccine series, they **do not need to restart** the vaccine series in the United States. They should receive the second dose as close to the recommended time as possible and are considered fully vaccinated upon completion of the 2-dose primary series. This also applies to people who were vaccinated in countries where only a single mRNA dose is administered; they are not considered fully vaccinated in the United States until after completion of the 2-dose series.

2. **People who completed all of the recommended doses of an WHO-EUL COVID-19 vaccine not approved or authorized by FDA, or people who completed a heterologous (mix and match) series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccines**:
   a. Are considered fully vaccinated.
   b. Under the CDC's Emergency Use Instructions (EUI), moderately or severely immunocompromised people aged ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people.
   c. Under the EUI, people aged ≥18 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, if they fall into one of the groups at increased risk for serious complications of COVID-19 or exposure to SARs-CoV-2 as detailed in Considerations for use of a COVID-19 vaccine booster dose.
3. **People who received only the first dose of a multidose WHO-EUL COVID-19 primary series that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO**:
   a. Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., 2-dose mRNA series or single Janssen dose), with a minimum interval of at least 28 days since receipt of the last dose of a non-FDA-approved/authorized vaccine.
   b. After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated.

	***These persons require medical consultation** 4. **Participants in clinical trials within or outside the United States who received all of the recommended "active" (not placebo) primary series doses of a WHO-EUL COVID-19 vaccine that is not FDA-approved or FDA-authorized or 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 (i.e., Novavax COVID-19 vaccine, Moderna COVID-19 vaccine in children aged 6-17 years)**: a. Are considered fully vaccinated. b. Unless they have received or plan to receive an additional dose through a clinical trial, under EUI, moderately or severely immunocompromised clinical trial participants aged ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in the Considerations for COVID-19 vaccination in moderately or severely immunocompromised people. c. Unless they have received or plan to receive a booster dose through a clinical trial, under EUI, clinical trial participants aged ≥18 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, if they fall into one of the groups at increased risk for serious complications of COVID-19 or exposure to SARs-CoV-2 as detailed in Considerations for use of a COVID-19 booster dose. d. 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 of 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: • Vaccine administration errors • Serious adverse events • Cases of Multisystem Inflammatory Syndrome • 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.

NC State Health Director's Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
Revised November 19th, 2021

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., mRNA-COMIRNATY/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-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. History of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia. 6. History of MIS-C or MIS-A.
Contraindications for Use of this Order	1. Do not administer the Janssen 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 Appendix C: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States*
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 Vaccination 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. 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 COVIDvax 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.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
Revised November 19th, 2021

Approved by: ___ _____ Date Signed: _11-19-2021_____

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

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 236.