**NC State Health Director’s Statewide Standing Order for**
FDA Authorized Janssen COVID-19 Vaccine Administration
**Revised October 29th, 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.

<table>
<thead>
<tr>
<th>COVID-19 Vaccination</th>
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</table>
| **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:

- 65 year and older, who present requesting a booster dose at least 6 months after completion of their primary series.
- 18 years of age or older, who work in or are long-term care facility residents and present requesting a booster dose at least 6 months after completion of their primary series.
- 18 or older who self-attest to:
  - an underlying medical condition thus higher risk of severe COVID-19 and present requesting a booster dose at least 6 months after completion of their primary series, based on their individual benefits and risks
  - or
  - an occupational or institutional exposure to COVID 19 (see the CDC’s examples of workers who may be eligible) and present requesting a booster dose at least 6 months after completion of their primary series, based on their individual benefits and risks

**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:

<table>
<thead>
<tr>
<th>Single Dose of Janssen to Booster Dose of Janssen</th>
<th>** + End of 2 OR 3-dose mRNA series (Moderna or Pfizer/ COMIRNATY) to booster dose of Janssen</th>
</tr>
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<tbody>
<tr>
<td>2 months</td>
<td>6 months</td>
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**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](https://www.fda.gov/media/146304/download)
   b. **Vaccine Product and Dosing**:
      - **Primary Vaccination (Single Dose)**: Administer 0.5 mL Janssen COVID-19 Vaccine. This vaccination is administered as a single dose primary vaccination.
      - **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)*

+ 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:

<table>
<thead>
<tr>
<th>Sex and Weight of Patient</th>
<th>Needle Gauge</th>
<th>Needle Length</th>
<th>Injection Site</th>
</tr>
</thead>
</table>
| 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        | 1-1/2"        | Deltoid muscle of arm *
| Male 153–260 lbs.                 | 22–25        | 1-1/2"        | 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**).

- **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](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)

- **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.

e. **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).**

f. **Documentation:**
- CVMS: Document vaccine record in CVMS within 24 hours after vaccine administration per system guidelines found at:
NC State Health Director’s Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
Revised October 29th, 2021

| Special Circumstances | Patients vaccinated with COVID-19 vaccines not authorized or approved in the United States: These patients require a medical consultation. Limited data are available on the safety or efficacy of receiving a COVID-19 vaccine currently authorized or approved in the United States after receipt of a non-FDA-authorized or non-FDA-approved COVID-19 vaccine |

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.

- **Electronic Medical Record:** If necessary, for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.
- 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:
   
   e. **30 minutes:**
   1. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy
   2. Persons with a history of anaphylaxis due to any cause
   3. 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).
   
   f. **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.
NC State Health Director’s Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
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Vaccine. However, in some circumstances people who received a COVID-19 vaccine not currently authorized or approved in the United States may be offered revaccination with an FDA-authorized or FDA-approved vaccine:

1. COVID-19 vaccines not authorized or approved by FDA but listed for emergency use by World Health Organization (WHO):
   a. Patients who completed a COVID-19 vaccination series with a vaccine that has been listed for emergency use by the WHO do not need any additional doses with an FDA-authorized or FDA-approved COVID-19 vaccine.
   b. Patients who are partially vaccinated with a COVID-19 vaccine series listed for emergency use by WHO may be offered a complete FDA-authorized or a FDA-approved COVID-19 vaccine series. Wait at least 28 days after the last dose of a non-FDA-authorized or non-FDA-approved vaccine or a WHO-listed vaccine before administering an FDA-authorized or FDA-approved COVID-19 vaccine.

2. COVID-19 vaccines not authorized or approved by FDA or not listed for emergency use by WHO: Patients who completed or partially completed a COVID-19 vaccine series with a vaccine that is not authorized or approved by FDA or not listed for emergency use by WHO may be offered a complete FDA-authorized or complete FDA-approved COVID-19 vaccine series. Wait at least 28 days after the last dose of a non-FDA-authorized or a non-FDA-approved vaccine or a WHO-listed vaccine before administering an FDA-authorized or FDA-approved COVID-19 vaccine.

3. Administration of an FDA-authorized or FDA-approved COVID-19 vaccine in these patients should comply with all conditions of use specified under the EUA or FDA approval for the vaccine being used.

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.gov](https://vaers.hhs.gov) 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., 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.
NC State Health Director’s Statewide Standing Order for
FDA Authorized Janssen COVID-19 Vaccine Administration
Revised October 29th, 2021

<table>
<thead>
<tr>
<th>Consultation with an allergist-immunologist should be considered prior to vaccination and patients with this precaution should be vaccinated in a healthcare setting where allergic reactions can be immediately managed and under the supervision of a healthcare provider experienced in the management of severe allergic reactions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Patient self-reported moderate to severe acute illness.</td>
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<tr>
<td>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.</td>
</tr>
<tr>
<td>5. History of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia.</td>
</tr>
</tbody>
</table>

**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.

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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.