

Template Non-Patient-Specific Standing Order for the Administration of the Janssen COVID-19 Vaccination in New York State

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Janssen COVID-19 vaccination as permitted by its Emergency Use Authorization (EUA) to individuals in accordance with the Centers for Disease Control and Prevention's (CDC) Vaccination Program and recommendations issued by the Advisory Committee on Immunization Practices (ACIP).

Policy: Under this non patient-specific standing order, [insert clinical staff titles] who are [employees, volunteers, [and/or] contractors] of the [Insert Organization Name] and who meet and/or have satisfied all applicable requirements to administer vaccination as set forth in law and by Executive Orders 202.82, 202.86, and 202.90 and any other relevant Executive Orders that may extend, modify, add to, or expand upon the provisions in EOs 202.82, 202.86, and 202.90, as extended, may administer the Janssen COVID-19 vaccination to individuals age 18 years and older who are eligible for COVID-19 vaccine at the time they are vaccinated, as permitted by its Emergency Use Authorization (EUA) to individuals in accordance with the CDC's Vaccination Program and recommendations issued by ACIP.

Procedure:

1. Assess persons 18 years of age or older for eligibility for Janssen COVID-19 vaccine based on the following criteria:
 - a. No previous doses of any COVID-19 vaccine: Administer a single dose of Janssen COVID-19 vaccine according to the procedure described herein.
 - b. One (1) previous dose of an mRNA COVID-19 vaccine (i.e., Pfizer or Moderna COVID-19 vaccine) administered 28 or more days prior to the date of vaccine administration: Where possible, refer the individual to the location where they received their first dose or administer a second dose of the same vaccine according to procedures described in the standing order for that vaccine. However, if the individual cannot complete the series with the same vaccine, then a single dose of Janssen COVID-19 vaccine may be administered according to the procedure described herein, a minimum of 28 days after the dose of mRNA COVID-19 vaccine.
 - c. Janssen COVID-19 vaccine should not be administered at the same time as other vaccines. Counsel patients who have received other vaccine(s) within the previous 14 days on the unknown risks and benefits of administration of Janssen COVID-19 vaccine within 14 days of other vaccines.
 - d. Janssen COVID-19 vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment in order to avoid interference of antibody therapy with vaccine-induced immune responses.
2. Screen for contraindications and precautions

- a. **Contraindications:** Do not administer the Janssen COVID-19 vaccine to anyone with a known history of a severe allergic reaction (e.g., anaphylaxis), an immediate allergic reaction of any severity (defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress, or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication) or a known (diagnosed) allergy to any of the Janssen COVID-19 vaccine’s components (including polysorbate) listed in the prescribing information at <https://www.fda.gov/media/146304/download>.
- b. **Precautions:**
 - i. Defer administering the Janssen vaccine to people who are moderately to severely ill with an acute illness until they have recovered.
 - ii. In persons who report a history of an immediate allergic reaction to any other (not COVID-19) vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous, excluding subcutaneous immunotherapy for allergies, i.e. “allergy shots”), counsel about the unknown risks of developing a severe allergic reaction and the risks and benefits of COVID-19 vaccination, and consider deferral of vaccination until further information on risk of anaphylaxis is available and/or consultation with an allergist-immunologist.
 1. This precaution does not apply to allergic reactions unrelated to vaccines, injectable therapy or components of the Janssen vaccine (e.g., pet, venom, environmental, food, latex or oral medications, or a family history of allergies).
 - iii. The following people with contraindications to mRNA COVID-19 vaccines have precautions to Janssen COVID-19 vaccine. However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the [Clinical Immunization Safety Assessment COVIDvax](#) project. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. [Insert the Organization’s procedure to refer these individuals for further evaluation and management].
 1. Persons with a history of severe or immediate allergic reaction to an mRNA COVID-19 vaccine (i.e., Moderna or Pfizer COVID-19 vaccine) due to potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, and
 2. Persons with a history of immediate allergic reaction of any severity to polyethylene glycol (PEG) due to potential cross-reactive hypersensitivity between PEG and ingredients in the Janssen COVID-19 vaccine.
3. Provide information on the Janssen COVID-19 vaccine and obtain consent.

- a. Prior to vaccine administration:
 - i. Inform each patient or a patient’s legal guardian, as applicable, of the risks, benefits, and alternatives of receiving the COVID-19 vaccine.
 - As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving Janssen COVID-19 Vaccine, including: (1) FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA-approved vaccine; (2) The recipient or their caregiver has the option to accept or refuse Janssen COVID-19 Vaccine; (3) The significant known and potential risks and benefits of Janssen COVID-19 Vaccine, and the extent to which such risks and benefits are unknown; and (4) Information about available alternative vaccines and the risks and benefits of those alternatives.
 - ii. Provide each patient or patient’s legal guardian, as applicable, a copy of the “Fact Sheet for Recipients and Caregivers,” or direct the individual to the website <https://www.fda.gov/media/146305/download> to obtain the Fact Sheet.
 - iii. Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.
 - iv. Obtain verbal consent to administer the vaccine from the patient or the patient’s legal guardian, as applicable. [Insert how the Organization will be documenting consent and what forms will be used].

4. Storage and Handling of Vaccine

- a. Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen. Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.
- b. If vaccine is frozen upon delivery, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. **Do not refreeze once thawed.**

- c. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

5. Prepare to administer vaccine

- a. Janssen COVID-19 vaccine vials do not contain preservatives. Strict adherence of aseptic technique during administration must be followed.
- b. Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. Do not shake. Do not dilute the vaccine.
- c. Inspect the liquid in the vial prior to administration. The liquid is a colorless to slightly yellow, clear to very opalescent suspension. Do not use if liquid is discolored or if particles are observed. Notify the NYSDOH at 1-800-543-7468 if you need to discard vaccine.
- d. Visually assess patient weight and select a needle for vaccine administration based on the following chart:

Patient Gender	Patient Weight	Needle Length
Female	< 130 lbs	5/8* – 1”
	130–152 lbs	1”
	153–200 lbs	1–1½”
	200+ lbs	1½”
Male	< 130 lbs	5/8* – 1”
	130–152 lbs	1”
	153–260 lbs	1–1½”
	260+ lbs	1½”

*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. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.5 mL of the Janssen COVID-19 Vaccine. Do not pool excess vaccine from multiple vials.
- f. After the first dose has been withdrawn, the vial should be held between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F). Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. Discard if vaccine is not used within these times.

6. Administer vaccine

- a. Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension.
 - i. Verify the final dosing volume of 0.5 mL.
 - ii. Confirm there are no particulates and that no discoloration is observed.
 - iii. Do not administer if vaccine is discolored or contains particulate matter.

- iv. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter.
- b. Administer the Janssen COVID-19 Vaccine, 0.5 mL, in the deltoid muscle (preferred site) or the anterolateral thigh (alternate site) via the intramuscular (IM) route.

7. Document vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical Record System: Ensure that the patient's name, the date the vaccine was administered, the name of the vaccine, the manufacturer and lot number, the vaccination site and route, address of administering site, and the name and title of the authorized vaccinator administering the vaccine, the publication date of the EUA fact sheet and the date it was given to the patient is documented in the patient's medical record or on a separate form retained by the authorized vaccinator who has administered the immunization, and in a retrievable format available to the State Education Department and the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, refusal). Documentation must be completed within 24 hours of administration. This information, whether in a medical record or separately kept, must be recorded and maintained in accordance with 8 NYCRR section 29.2 (a) (3).

Signed Certificate of Immunization (given to the patient): Record the patient's name, date of vaccination, name/location of the administering clinic, administering nurse, name of vaccine, manufacturer and lot number.

New York State Immunization Information System (NYSIIS) and City Immunization Registry (CIR): Report all doses administered to NYSIIS or CIR within 24 hours of administration.

8. Management of medical emergencies

Observe all patients for the following observation periods following vaccination to monitor for the occurrence of immediate adverse reactions:

- 30 minutes:
 - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy, and
 - History of anaphylaxis due to any cause.
- 15 minutes: All other people.

Be prepared for management of a medical emergency related to the administration of vaccine by maintaining written copies of the standing orders and protocols for administration of epinephrine and diphenhydramine. RNs shall be responsible for having emergency anaphylaxis treatment

agents, related syringes and needles at the immunization site, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and a stethoscope and timing device to assess pulse. To prevent syncope, vaccinate patients while they are seated or lying down and assess for signs of syncope such as extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness or visual disturbances.

For more information, please see:

- Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination sites at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>
- CDC’s General Best Practice Guidelines for Immunization, “Preventing and Managing Adverse Reactions,” at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf>
- Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting” at <https://www.immunize.org/catg.d/p3082.pdf>.

9. Reporting of adverse events

- a. Report the following information associated with the administration of Janssen COVID-19 vaccine of which they become aware to Vaccine Adverse Events Electronic Reporting System (VAERS) in accordance with the “Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers),” including:
 - i. Vaccine administration errors whether or not associated with an adverse event
 - ii. Serious adverse events (irrespective of attribution to vaccination)¹
 - iii. Cases of Multisystem Inflammatory Syndrome in adults
 - iv. Cases of COVID-19 that result in hospitalization or death.
- b. Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words “Janssen COVID-19 Vaccine EUA” in the description section of the report.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

¹ Serious adverse events are defined as: (1) Death; (2) A life-threatening adverse event; (3) Inpatient hospitalization or prolongation of existing hospitalization; (4) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; (5) A congenital anomaly/birth defect; or (6) An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

To the extent feasible, report adverse events to Janssen Biotech, Inc. using the contact information below or by providing a copy of the VAERS form to Janssen Biotech, Inc:

Email: JNJvaccineAE@its.jnj.com

Fax: 215-293-9955

Phone US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

- c. Conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

Order: In accordance with Governor Cuomo’s Executive Order Nos. 202.82, 202.86, and 202.90, as extended, (and any other relevant Executive Orders that may extend, modify, add to, or expand upon the provisions in the above referenced EOs), any relevant laws for authorized vaccinators permitted to administer vaccinations under this Order, and subject to the Purpose, Policy and Procedure set forth herein, I am hereby prescribing this non patient-specific order for the administration of Janssen COVID-19 Vaccine statewide [insert dates of clinics and locations]. Specifically, [insert staff titles] who are employees, volunteers, or contractors of the [Insert Organization] may administer Janssen COVID-19 Vaccine as permitted by its Emergency Use Authorization (EUA) to individuals age 18 years and older who are eligible for COVID-19 vaccine at the time they are vaccinated in accordance with the CDC Vaccination Program and recommendations issued by the ACIP, and such other relevant Executive Orders.

This non patient-specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on [insert date] through [insert date]. In the event that I discontinue this non patient-specific order prior to [insert end date as listed above], notice of such discontinuance shall be provided to those [Insert Organization] employees and contractors permitted to execute under this Order via [insert how employees and contractors will be notified of a discontinuance].

Signature: _____ Date: _____

Name of Physician: _____

Title: _____

Institution: _____

NYS License No.: _____

Effective Date of Order: _____