**Non Patient-Specific Standing Order for the Administration of the**

**Purple Cap Pfizer-BioNTech COVID-19 Vaccine**

**(Updated 01/12/2022)**

**Purpose:** To reduce morbidity and mortality from COVID-19 by administering the “**purple cap**” Pfizer-BioNTech COVID-19 vaccination as permitted by the policy and order sections of this Order.

**Policy:** Under this non patient-specific standing order, [insert clinical staff titles] who are [employees, volunteers, [and/or] contractors] of the [Insert Organization Name] may administer the Pfizer-BioNTech COVID-19 vaccination to eligible individuals, as permitted by its Emergency Use Authorization (EUA), as applicable, state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, ACIP recommendations, and the CDC’s and New York State’s Vaccination Program.

**Procedure:**

1. This standing order is for use of Pfizer-BioNTech COVID-19 vaccine vials with **purple caps** and labeled for use persons age 12 years and older.
	1. If using Pfizer-BioNTech COVID-19 vaccine vials with gray caps and labeled “Do Not Dilute”, consult the standing order for administration of Pfizer-BioNTech COVID-19 gray cap vaccine vials.
	2. If vaccinating persons between the ages of 5 through 11 years, consult the standing orders for administration of Pfizer-BioNTech COVID-19 vaccine to children age 5 through 11 years.
2. Assess persons 12 years of age or older for eligibility for Pfizer-BioNTech COVID-19 vaccine based on the following criteria:
	1. Primary (initial) vaccine series:
		1. No COVID-19 vaccine or either a complete or incomplete series of COVID-19 vaccine product that holds neither an Emergency Use Listing (EUL) by the World Health Organization (WHO) nor an EUA nor approval by the US Food and Drug Administration (FDA): Administer the first dose of Pfizer BioNTech COVID-19 vaccine according to the procedure described herein.
		2. One (1) previous dose of Pfizer BioNTech COVID-19 vaccine administered 21 or more days prior to the date of vaccine administration: Administer the second dose of Pfizer BioNTech COVID-19 vaccine according to the procedure described herein.
		3. An incomplete primary dose series of a COVID-19 vaccine product that holds an EUL by the WHO but does not hold an EUA by the FDA (e.g., only the first dose of a two-dose primary series) with the most recent dose 28 or more days prior to the date of vaccine administration: administer one dose of the Pfizer-BioNTech COVID-19 vaccine to complete the primary series.
		4. Administer one additional dose of Pfizer BioNTech COVID-19 vaccine to persons with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, such as at least 1 of the following immunocompromising conditions, at least 28 days after their second dose of an mRNA COVID-19 vaccine within a primary series:
			1. Active treatment for solid tumor and hematologic malignancies;
			2. Receipt of solid-organ transplant and taking immunosuppressive therapy;
			3. Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
				1. If one or more doses of any mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) were received prior to CAR-T cell or hematopoietic stem cell transplant, revaccinate with a new primary series and a new additional dose of Pfizer-BioNTech COVID-19 vaccine at least 12 weeks after CAR-T cell therapy or transplant.
			4. Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
			5. Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV infection)
			6. Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.
	2. Booster dose eligibility
		1. Age 12 years or older and receipt of a complete primary series of the Pfizer-BioNTech COVID-19 vaccine with the final dose received at least five (5) months prior (i.e., after the 2nd dose or the additional [3rd] dose for moderately or severely immunocompromised persons), OR
		2. Age 18 years or older and receipt of a complete primary series of the Moderna COVID-19 vaccine with the final dose received at least five (5) months prior (i.e., after the 2nd dose or the additional [3rd] dose for moderately or severely immunocompromised persons), OR
		3. Age 12 years or older and receipt of a complete primary series of COVID-19 vaccines listed for emergency use by the World Health Organization (WHO) – either as a homologous (same vaccine for both doses) or heterologous (mix and max) series – with the final dose received at least five (5) months prior (i.e., after the 2nd dose or the additional [3rd] dose for moderately or severely immunocompromised persons), OR
		4. Age 18 years or older and receipt of a single dose of Janssen/Johnson & Johnson COVID-19 vaccine at least two (2) months prior.
3. Screen for contraindications and precautions
	1. **Contraindications:** Do not administer the Pfizer-BioNTech COVID-19 vaccine to anyone with a known history of:
		1. a severe allergic reaction (e.g., anaphylaxis) to a prior dose of an mRNA COVID-19 vaccine (i.e., Moderna or Pfizer-BioNTech COVID-19 vaccines) or
		2. diagnosed allergy to any vaccine component (including polyethylene glycol) listed in the prescribing information at <https://www.fda.gov/media/144413/download>.
	2. **Precautions:**
		1. Defer administering the Pfizer-BioNTech COVID-19 vaccine to people who are moderately to severely ill with an acute illness until they have recovered.
		2. Defer administering Pfizer-BioNTech COVID-19 vaccine, as a precautionary measure in order to avoid interference of antibody therapy with vaccine-induced immune responses, to persons who received passive antibody products (monoclonal antibodies or convalescent plasma) for the following time periods:
			1. Passive antibody product used as post-exposure prophylaxis: defer COVID-19 vaccination for 30 days;
			2. Passive antibody product used for COVID-19 treatment: defer COVID-19 vaccination for 90 days.
		3. Consider deferral of vaccination of persons with history of immediate (within 4 hours after vaccination) non-severe allergic reaction to a previous dose of any COVID-19 vaccine pending consultation with an allergist-immunologist.
		4. Consider deferral of vaccination of persons with a history of an immediate allergic reaction to a non-COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of the Pfizer-BioNTech COVID-19 vaccine (excluding subcutaneous immunotherapy for allergies, i.e. “allergy shots”) pending consultation with an allergist-immunologist.
			1. This does not apply to persons with allergies unrelated to vaccines or injectable therapy (e.g., oral medications, animals, insects, venom, environmental, food, latex, etc.)
		5. History of myocarditis or pericarditis:
			1. After receiving a previous dose of an mRNA COVID-19 vaccine: Defer administration of additional doses of mRNA COVID-19 vaccine. Administration of additional doses of mRNA COVID-19 vaccine can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions>
			2. Prior to COVID-19 vaccination: Defer administration of mRNA COVID-19 vaccine until after the episode of myocarditis or pericarditis has completely resolved. After resolution of episode, may receive any FDA-approved or -authorized COVID-19 vaccine.
		6. The following people with contraindications to Janssen COVID-19 vaccines have precautions to the Pfizer-BioNTech 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](https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html). 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. If a patient should present under this scenario, [Insert the Organization’s procedure to refer these individuals for further evaluation and management].
			1. Persons with a history of severe allergic reaction to the Janssen COVID-19 vaccine due to potential cross-reactive hypersensitivity between ingredients in the Janssen and Pfizer COVID-19 vaccines, and
			2. Persons with a history of immediate allergic reaction of any severity to polysorbate due to potential cross-reactive hypersensitivity between polysorbate and ingredients in the Pfizer-BioNTech COVID-19 vaccine.
4. Provide information on the Pfizer-BioNTech COVID-19 vaccine and obtain consent.
5. Prior to vaccine administration:
6. 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 Pfizer-BioNTech COVID-19 Vaccine, including: **(1)** The Pfizer-BioNTech COVID-19 vaccine is FDA-approved as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older and is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and as a booster dose for ages 12 years and up; **(2)** The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine; **(3)** The significant known and potential risks and benefits of Pfizer-BioNTech 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.
1. 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 <https://www.fda.gov/media/144414/download> to obtain the Fact Sheet.
2. Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe.. For more information, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).
3. 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. Provide necessary information on receiving the second dose of vaccine.
5. When administering the first dose of Pfizer-BioNTech COVID-19 vaccine, provide a vaccination card to the recipient or their caregiver with the location and date in 21 days when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.
6. Storage and Handling of Vaccine
7. Pfizer-BioNTech COVID-19 vaccines contain preservative-free frozen suspension that must be stored at appropriate temperatures to preserve efficacy. Consult CDC, NYSDOH and Pfizer guidance on storage and handling of Pfizer-BioNTech COVID-19 vaccines.
8. Pfizer-BioNTech COVID-19 **purple cap** vaccine vials must be thawed prior to dilution and administration. Only thaw the number of vials that you believe you will need. Thawed vials cannot be refrozen. Each multi-dose vial contains enough suspension for six patients.
9. Thawing under refrigeration: A full tray of 25 or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator. A smaller number of vials will thaw in less time.
10. Thawing at room temperature: Vials will thaw at room temperature (up to 25 ⁰C [77 ⁰F]) in 30 minutes. Undiluted vials may be stored at room temperature for no more than 2 hours.
11. Once diluted, doses must be used within 6 hours after which any remaining doses must be discarded.
12. Pfizer-BioNTech COVID-19 vaccine vials must reach room temperature prior to dilution.
13. Store diluent vials at room temperature.
14. Prepare to administer vaccine
15. Carefully inspect the vial prior to vaccine preparation. Confirm that the vial has a **purple cap** and is labeled “DILUTE BEFORE USE” and for ages 12 years and older. If the vial has a gray cap, then consult the standing orders for Pfizer-BioNTech gray cap vaccine vials for vaccine preparation instructions.
16. Pfizer-BioNTech COVID-19 vaccine vials do not contain preservatives. Strict adherence of aseptic technique during dilution and administration must be followed.
17. Ensure the vaccine vial has thawed to room temperature prior to dilution. If a vial feels cold to the touch, then it has not thawed enough.
18. Gently invert the vaccine vial ten (10) times to mix. Do not shake. Shaking can impair the efficacy of the vaccine.
19. Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discolored or if other particles are observed.
20. Dilution:
	1. Carefully inspect the vial prior to vaccine preparation. Confirm that the vial has a **purple cap** and is labeled “DILUTE BEFORE USE” and for ages 12 years and older. **Do not dilute Pfizer-BioNTech vaccine vials with gray caps labeled “Do Not Dilute”**. Consult the standing orders for Pfizer-BioNTech gray cap vaccine vials for “gray cap” vaccine preparation instructions.
	2. Use only sterile 0.9% Sodium Chloride Injection, USP as diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection as this may impair the efficacy of the vaccine.
	3. Using aseptic technique, withdraw 1.8 mL of 0.9% Sodium Chloride diluent into a 3 mL or 5 mL transfer syringe, using a 21-gauge or narrower needle.
	4. Cleanse the vaccine vial stopper with a single-use antiseptic swab.
	5. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
	6. Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	7. Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. Do not shake.
	8. Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter. Call the manufacturer and the New York State Department of Health (NYSDOH) if this occurs.
	9. Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. Store diluted vaccine between 2°C to 25°C (35°F to 77°F) for a maximum of 6 hours after dilution. Discard any unused diluted vaccine 6 hours after dilution. Notify the NYSDOH at 1-800-543-7468 if you need to discard vaccine.
21. 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 vaccine recipients who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

1. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine.
2. Administer vaccine
3. Visually inspect each dose in the dosing syringe prior to administration.
	1. Verify the final dosing volume of 0.3 mL.
	2. Confirm there are no particulates and that no discoloration is observed.
	3. Do not administer if vaccine is discolored or contains particulate matter.
	4. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter.
4. Administer the Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL, in the deltoid muscle via the intramuscular (IM) route.
5. Document vaccination

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

**Medical Record System (including CDMS, as applicable):** 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 vaccinator, name of vaccine, manufacturer and lot number, and recommendations for future immunizations.

**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. [If using CDMS] With respect to NYSIIS, if the dose was documented in CDMS, then the NYSDOH shall transmit data from CDMS to NYSIIS for all patients.

1. Authorized vaccinators must inform vaccine recipients age less than 18 years and the adult caregiver accompanying such patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.
2. 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:
	+ People with a contraindication to Janssen COVID-19 vaccine who receive Pfizer-BioNTech COVID-19 vaccine,
	+ History of non-severe, immediate (less than 4 hours) allergic reaction after a previous dose of COVID-19 vaccine,
	+ 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>.
* Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Children and Teens in a Community Setting” at <https://www.immunize.org/catg.d/p3082a.pdf>.
1. Reporting of adverse events
2. Report the following information associated with the administration of Pfizer BioNTech 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:
3. Vaccine administration errors whether or not associated with an adverse event
4. Serious adverse events (irrespective of attribution to vaccination)[[1]](#footnote-1)
5. Cases of Multisystem Inflammatory Syndrome in children and adults
6. Cases of COVID-19 that result in hospitalization or death
7. Any additional adverse events and revised safety requirements per the Food and Drug Administration’s conditions for use of an authorized vaccine throughout the duration of the EUA.
8. Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The VAERS reports should include the words “Pfizer-BioNTech COVID‑19 Vaccine EUA” in the description section of the report. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.
9. 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:** I am hereby prescribing this non patient-specific order for the administration of Pfizer-BioNTech COVID‑19 Vaccine to persons age 12 years or older on [insert dates and locations].Specifically, [insert staff titles] who are employees, volunteers, or contractors of the [Insert Organization] may administer the Pfizer-BioNTech COVID‑19 Vaccine, as permitted by its Emergency Use Authorization (EUA), as applicable, state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, ACIP recommendations, and the CDC’s and New York State’s Vaccination Program.

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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NYS License No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Effective Date of Order: \_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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. [↑](#footnote-ref-1)