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

**the Pfizer-BioNTech COVID-19 Vaccination to Children Age 5 through 11 Years**

**(Updated 05/23/22)**

**Purpose:** To reduce morbidity and mortality from COVID-19 by administering the 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 children age 5 through 11 years, 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 **orange caps** and labeled for use persons 5 through 11 years of age.
	1. If vaccinating persons age 12 years and older, refer to the non-patient specific standing order for the administration of the Pfizer-BioNTech COVID-19 vaccination to ages 12 years and older.
2. Assess children 5 through 11 years of age for eligibility for Pfizer-BioNTech COVID-19 vaccine based on the following criteria:
	1. Primary series:
		1. No previous doses of COVID-19 vaccine: Administer the first dose of Pfizer BioNTech COVID-19 vaccine according to the procedure described herein.
		2. Prior receipt of an incomplete series of a COVID-19 vaccine product that holds an emergency use listing (EUL) by the World Health Organization (WHO) but does not hold 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.
		3. Prior receipt of either a complete or incomplete series of COVID-19 vaccine product that holds neither an EUL by the WHO nor an EUA nor approval by the US FDA: Administer the first dose of Pfizer BioNTech COVID-19 vaccine according to the procedure described herein.
		4. 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.
	2. Additional primary dose: 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)
		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 (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.
	3. Booster dose. Administer one 10µg booster dose of Pfizer-BioNTech COVID-19 vaccine to individuals ages 5-11 years who meet the following criteria:
		1. Prior receipt of a complete primary series of Pfizer-BioNTech COVID-19 vaccine, a COVID-19 vaccine that holds an EUL by the WHO, or of a heterologous series of COVID-19 vaccines that hold an EUL by the WHO and Pfizer-BioNTech COVID-19 vaccine.
		2. A period of at least 3 months has passed since receipt of the final dose of the primary series (3 doses) if moderate to severe immune compromise, or a period of at least 5 months has passed since receipt of the primary series (2 doses) for all others.
	4. Revaccination: Recipients of hematopoietic stem cell transplant, CAR-T-cell, or other B-cell depleting therapies who received doses of COVID-19 vaccine prior to or during treatment should be revaccinated for all doses received before or during treatment, with the first revaccinated dose given at least 12 weeks after completing treatment. Based on the clinical judgement of the patient’s clinical team, revaccination may also be considered once immune competence is regained for people who received COVID-19 vaccine doses during chemotherapy or radiation treatment.
		1. Revaccination may also be considered for patients who received one or more doses of COVID-19 vaccine **during treatment** with B-cell-depleting therapies (e.g., rituximab, ocrelizumab) that were administered **over a limited period** (e.g., as part of a treatment regimen for certain malignancies). The suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy.
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 the Pfizer-BioNTech COVID-19 vaccine to people with known current SARS-CoV-2 infection at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
		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 until further information on risk of anaphylaxis is available and/or consultation with an allergist-immunologist.
		4. Defer administering the Pfizer-BioNTech COVID-19 vaccine to persons with a history of severe allergic reaction to the Janssen COVID-19 vaccine or a diagnosed allergy to a component of the Janssen COVID-19 vaccine (such as polysorbate) because of potential cross-reactive hypersensitivity between ingredients in the Janssen and Pfizer-BioNTech COVID-19 vaccines. 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].
		5. 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.)
		6. History of myocarditis or pericarditis:
			1. Onset 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#considerations-pfizer-biontech-moderna>
			2. Onset 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 age-appropriate FDA-approved or -authorized COVID-19 vaccine.
		7. History of multisystem inflammatory syndrome in children (MIS-C)
			1. Onset before receiving a first dose of COVID-19 vaccine: Defer administration of COVID-19 vaccine until clinical recovery has been achieved as assessed by the vaccine recipient’s treating team, including return to normal cardiac function, and until at least 90 days after their MIS-C diagnosis. [Insert the Organization’s procedure to refer these individuals for further evaluation and management].
			2. Onset after receiving a previous dose of any COVID-19 vaccine:
				1. If onset occurred 90 or more days after the date of the most recent COVID-19 vaccine dose, defer administration of COVID-19 vaccine until

clinical recovery has been achieved as assessed by the vaccine recipient’s treating team, including return to normal cardiac function,

at least 90 days after their MIS-C or MIS-A diagnosis, and

the patient resides in an area where the COVID-19 community level is high or is otherwise at increased risk for exposure to SARS-CoV-2 (e.g., through occupation, travel, large gatherings).

* + - * 1. If onset occurred fewer than 90 days after the date of the most recent COVID-19 vaccine dose, defer administration of subsequent doses of COVID-19 vaccine until additional data is available.
				2. COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and do not meet all three criteria, at the discretion of their clinical care team (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#:~:text=19%20vaccination.-,Consultation%20for%20decisions%20about%20COVID%2D19%20vaccination,-A%20conversation%20between). Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. [Insert the Organization’s procedure to refer these individuals for further evaluation and management].
1. Provide information on the Pfizer-BioNTech COVID-19 vaccine and obtain consent.
2. Prior to vaccine administration:
3. Inform each patient’s parent or legal guardian of the risks, benefits, and alternatives of receiving the COVID-19 vaccine.
* As the vaccination provider, you must communicate to the caregiver information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including: **(1)** a two-dose series of the Pfizer-BioNTech COVID-19 vaccine is authorized for emergency use by the FDA in children 5 through 11 years of age, and a third dose is authorized for certain immunocompromised children 5 through 11 years of age;; **(2)** The 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’s parent or legal guardian a copy of the “Fact Sheet for Recipients and Caregivers,” or direct the individual to <https://www.fda.gov/media/153716/download> to obtain the Fact Sheet.
2. Provide the v-safe information sheet to vaccine recipients’ caregivers and encourage them 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. Storage and Handling of Vaccine
5. 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.
6. Pfizer-BioNTech COVID-19 vaccines must be thawed prior to dilution and administration. Thawed vials cannot be refrozen. Each multi-dose vial contains enough suspension for ten patients.
7. Thawing under refrigeration: A carton of 10 vials may take up to 4 hours to thaw in the refrigerator.
8. 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 12 hours.
9. Once diluted, doses must be used within 12 hours after which any remaining doses must be discarded.
10. Pfizer-BioNTech COVID-19 vaccine vials must reach room temperature prior to dilution.
11. Store diluent vials at room temperature.
12. Prepare to administer vaccine
13. Pfizer-BioNTech COVID-19 vaccine vials do not contain preservatives. Strict adherence of aseptic technique during dilution and administration must be followed.
14. **Carefully inspect the vial prior to preparation**. The Pfizer-BioNTech COVID-19 vaccine for children 5 through 11 years of age has an **orange cap** and a label with an **orange** border. **Do not administer Pfizer-BioNTech vaccine from a vial with a purple or gray cap or label to children age less than 12 years**.
15. The Pfizer-BioNTech COVID-19 vaccine for children 5 through 11 years of age **must be diluted** to a 10µg dose prior to administration.
16. Before dilution, mix by gently inverting the vaccine vial ten (10) times. Do not shake. Shaking can impair the efficacy of the vaccine.
17. 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.
18. Dilution:
	1. 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.
	2. Using aseptic technique, withdraw 1.3 mL of 0.9% Sodium Chloride diluent into a 3 mL or 5 mL transfer syringe, using a 21-gauge or narrower needle.
	3. Cleanse the vaccine vial stopper with a single-use antiseptic swab.
	4. Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
	5. Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.
	6. Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. Do not shake.
	7. 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.
	8. 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 12 hours after dilution. Discard any unused diluted vaccine 12 hours after dilution. Notify the NYSDOH at 1-800-543-7468 if you need to discard vaccine.
19. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.
20. Administer vaccine
21. Visually inspect each dose in the dosing syringe prior to administration.
	1. Verify the final dosing volume of 0.2 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.
22. Using a 22-25 gauge 1 inch\* needle, administer the Pfizer-BioNTech COVID-19 Vaccine, 0.2 mL, in the deltoid muscle\*\* via the intramuscular (IM) route.

\*Some experts recommend a 5/8-inch needle for vaccine recipients who weigh less 130 pounds. If a 5/8-inch needle is used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

\*\*Although the deltoid muscle is the preferred site of IM vaccine administration in this age group, the vastus lateralis muscle in the anterolateral thigh can be used as an alternative site. Some larger children may need a 1 ½-inch needle to ensure IM administration when the vastus lateralis muscle is used.

1. 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 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. Management of medical emergencies

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

* 30 minutes:
	+ History of immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine,
	+ History of an immediate allergic reaction of any severity to a non-COVID-19 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 sufficient epinephrine to administer at least 3 doses to persons of any weight, 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 children 5 through 11 years of age 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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)