Non Patient-Specific Standing Order for the Administration of the PfizerBioNTech COVID-19 Vaccination for the Initial Phase of the COVID-19 Vaccination Program

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Pfizer- BioNTech COVID-19 vaccination as permitted by its Emergency Use Authorization (EUA) to individuals in accordance with the Center 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 description of the group of individuals being vaccinated, including age ranges

who have satisfied all applicable training requirements for vaccination as set forth in law and by Executive Order 202.82 may administer the Pfizer-BioNTech COVID-19 vaccination to

insert description of the group of individuals being vaccinated, including age ranges

, 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 for vaccine eligibility

a. Persons 16 years of age or older and in one or more of the current priority groups designated by the NYSDOH.

2. Screen for contraindications and precautions

a. **Contraindications**: Do not administer the Pfizer-BioNTech vaccine to anyone with a known history of a severe allergic reaction (e.g., anaphylaxis) to a prior dose of the Pfizer-BioNTech vaccine or to polyethylene glycol or any other vaccine component listed in the prescribing information at https://www.fda.gov/media/144413/download.

b. **Precautions:**

i. In persons who report a history of a severe allergic reaction (e.g., anaphylaxis) to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) conduct a risk assessment to determine the type of reaction and certainty of information. For example, whether the medication was administered via injection and whether the reaction constituted a severe allergic reaction (e.g., required use of epinephrine and/or hospitalization). Counsel these patients about the unknown risks of developing a severe allergic reaction and the benefits of COVID-19 vaccination, including the patient's current personal risks of COVID-19 and current COVID-19 transmission in their community. This precaution does not apply to persons with a mild allergic reaction, such as urticaria alone without signs or symptoms of anaphylaxis, nor to allergic reactions not related to vaccines or injectable therapy (e.g., pet, venom, environmental, food, latex or medications given orally).

ii. Defer administering the Pfizer-BioNTech vaccine to people who are moderately to severely ill with an acute illness until they have recovered.

iii. Defer administering the Pfizer-BioNTech vaccine for at least 90 days after receipt of antibody therapy for COVID-19 infection in order to avoid interference of antibody therapy with vaccine-induced immune responses.

iv. Defer administration of the Pfizer-BioNTech vaccine to anyone who has received a different vaccine in the last 14 days.

3. Provide information on the Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine, including: (1) FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine; (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.

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 www.cvdvaccine.com 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 consent to administer the vaccine from the patient or the patient's legal guardian, as applicable.

insert description of the group of individuals being vaccinated, including age ranges

b. Provide necessary information on receiving the second dose of vaccine.

4. Storage and Handling of Vaccine

a. 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.

b. Pfizer-BioNTech COVID-19 vaccines 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 five patients.

c. 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. Undiluted vials may remain in the refrigerator for up to 5 days.

d. Thawing at room temperature: Vials will thaw at room temperature (up to 25 ^{0}C [77 ^{0}F]) in 30 minutes. Undiluted vials may be stored at room temperature for no more than 2 hours. Do not thaw a vial at room temperature unless you are prepared to vaccinate 5 persons within two hours.

e. Pfizer-BioNTech COVID-19 vaccine vials must reach room temperature prior to dilution.

f. Store diluent vials at room temperature.

5. Prepare to administer vaccine

a. Pfizer-BioNTech COVID-19 vaccine vials do not contain preservatives. Strict adherence of aseptic technique during dilution and administration must be followed.

b. 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.

c. Gently invert the vaccine vial ten (10) times to mix. Do not shake. Shaking can impair the efficacy of the vaccine.

d. 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.

f. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.5 mL of the Moderna COVID-19 Vaccine.

g. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

f. 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)**.

g. 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.

6. Administer vaccine

a. Visually inspect each dose in the dosing syringe prior to administration.

a. Verify the final dosing volume of 0.3 mL.

b. Confirm there are no particulates and that no discoloration is observed.

c. Do not administer if vaccine is discolored or contains particulate matter.

d. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter.

b. Administer the Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL, in the deltoid muscle 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 (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 person administering the vaccine, the publication date of the EUA fact sheet and the date it was given to the patient is documented in CDMS. 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.

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, and recommendations for future immunizations. Request the patient to attest, in writing on the certificate of immunization, that they will provide a copy of the certificate to their primary care provider, if one exists.

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.

8. Licensed pharmacists must inform their 16 and 17-year-old vaccination patients 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.

9. Management of medical emergencies

Observe all patients for a minimum of 15 minutes following vaccination to monitor for the occurrence of immediate adverse reactions. Observe patients with a history of anaphylaxis for 30 minutes following vaccination.

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/info-by- product/pfizer/anaphylaxis-management.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.y will provide a copy of the certificate to their primary care provider, if one exists.

Order: In accordance with Governor Cuomo's Executive Order No. 202.82, and subject to the Purpose, Policy and Procedure set forth herein, I am hereby prescribing this non patient-specific order to administration of Pfizer-BioNTech COVID-19 Vaccine on

insert dates of testing and locations

Specifically, [insert staff titles]

insert staff titles

who are employees, volunteers, or contractors of the

insert Organization

may administer Pfizer-BioNTech COVID-19 Vaccine as permitted by its Emergency Use Authorization (EUA) to

insert description of the group of individual being vaccinated, including age ranges

, in accordance with the CDC Vaccination Program and recommendations issued by the ACIP.
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: _____

10. Reporting of adverse events

a. 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:

   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 children and 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 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.

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.

[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.