



**Non Patient-Specific Standing Order for the Administration of the
Pfizer-BioNTech Updated COVID-19 Vaccine (2023-2024 Formula)
for Persons 5 Years of Age and older
by Pharmacists
(Updated 06/21/2024)**

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) vaccination as permitted by the policy and order sections of this Order. Pursuant to 8 NYCRR § 63.9, the Commissioner of Health is authorized to issue a statewide standing order where he finds that there is an outbreak of disease, or that there is imminent threat of an outbreak of disease.

Policy: Under this non patient-specific standing order, pharmacists who are employees, volunteers, and/or contractors of all pharmacies licensed in New York State and who are pharmacists authorized to administer vaccines pursuant to a certificate of administration from the Department of Education under non-patient specific orders in New York State and who are certified in cardio-pulmonary resuscitation, may administer the Moderna COVID-19 Vaccine (2023-2024 Formula), to individuals ages 5 years and older, as permitted by its Biologics License Application (BLA) approval or Emergency Use Authorization, as applicable, by the U.S. Food and Drug Administration (FDA), state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, and the recommendations of the Advisory Committee on Immunization Practices (ACIP).

The 2023–2024 Pfizer formulation has been updated as a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2 and will be referred to as the “Pfizer COVID-19 Vaccine (2023-2024 Formula)” in this standing order.

Pfizer-BioNTech COVID-19 bivalent vaccine is no longer permitted to be used in any circumstance.

NOTE: Pharmacists must follow the requirements set forth in 8 NYCRR 63.9, including providing patients with requisite information, maintaining adequate records and adhering to reporting requirements.

Procedure: This standing order is for use of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) single dose vials or prefilled, single-dose syringes for persons 12 years of age and older administered intramuscularly and single dose vials for persons 5 years of age and older.

1. Assess individuals 5 years of age and older *who are NOT moderately to severely immunocompromised* for eligibility for Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) based on the following criteria and administer dose(s) according to the table below.

COVID-19 Vaccination history prior to updated (2023-2024 Formula)	Number of Pfizer-BioNTech COVID-19 (2023-2024 Formula) doses indicated	Dosage	Vaccine vial cap and label border colors*	Interval between doses
Unvaccinated	1	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	--
1 or more doses any mRNA vaccine	1	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	At least 8 weeks after last dose
1 or more doses Novavax or Janssen, including in combination with any mRNA vaccine dose(s)	1	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	At least 8 weeks after last dose

*Vials come with gray cap and gray label border for those ages 12 and older. For those 5-11, the vials come with a blue cap and blue label border. Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is also available in a prefilled, single-dose plastic syringe and as a prefilled, single-dose glass syringe for people ages 12 years and older, both with gray border on the label.

Note 1: Children who transition from age 11 years to age 12 years during the Pfizer-BioNTech initial vaccination series are recommended to receive updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 ug (gray cap; gray label border) for all doses received on or after turning age 12 years. However, the [FDA EUA](#) provides that they may also receive the dosage for children ages 5–11 years, 0.3 mL/10 ug.

Note 2: People 65 years and older should receive 1 additional dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 4 months following the previous dose of updated (2023–2024 Formula) COVID-19 vaccine.

For more information, please see [CDC’s Interim Clinical Considerations Appendix A](#).

2. Assess individuals aged 5 years and older *who are moderately to severely immunocompromised* and administer Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) dose(s) according to the table below.

COVID-19 Vaccination history prior to updated (2023-2024 Formula)	Number of Pfizer-BioNTech COVID-19 (2023-2024 Formula) doses indicated	Dosage	Vaccine vial cap and label border colors*	Interval between doses
Unvaccinated	3	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	Dose 1 and Dose 2: at least 3 weeks Dose 2 and dose 3: at least 4 weeks
1 dose any Pfizer-BioNTech	2	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	Dose 1: at least 3 weeks after last dose Dose 1 and dose 2: at least 4 weeks
2 doses any Pfizer-BioNTech	1	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	At least 4 weeks after last dose
3 or more doses any mRNA vaccine NOT including at least 1 dose of 2023-2024 COVID-19 vaccine	1	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	At least 8 weeks after last dose
1 or more doses of Novavax or Janssen vaccine, including in combination with any mRNA vaccine dose(s)	1	0.3 mL/30 ug (ages ≥12 years) OR 0.3 mL/10ug (ages 5 years to 11 years)	Gray cap; gray label border or prefilled syringe (ages ≥12) OR blue cap; blue label border (ages 5-11)	At least 8 weeks after last dose

*Vials come with gray cap and gray label border for those ages 12 and older. For those 5-11, the vials come with a blue cap and blue label border. Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is also available in a prefilled, single-dose plastic syringe and as a prefilled, single dose glass syringe for people ages 12 years and older, both with gray border on the label.

Note 1: Children who transition from age 11 years to age 12 years during the Pfizer-BioNTech initial vaccination series are recommended to receive updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 ug (gray cap; gray label border) for all doses received on or after turning age 12 years. However, the [FDA EUA](#) provides that they may also receive the dosage for children ages 5–11 years, 0.3 mL/10 ug.

Note 2: People ages 5 – 64 years who are moderately or severely immunocompromised may receive 1 additional dose of an updated (2023–2024 Formula) COVID-19 vaccine at least 2 months following the previous dose of updated (2023–2024 Formula) vaccine. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

Note 3: People ages 65 years and older who are moderately or severely immunocompromised should receive 1 additional dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 2 months following the previous dose of updated (2023–2024 Formula) COVID-19 vaccine.

Please note that the COVID-19 vaccine used for the additional doses varies by age and vaccination history.

Additional Clinical Considerations

- Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) may be simultaneously administered with other routinely recommended vaccines. There are additional considerations for simultaneous administration of an orthopoxvirus vaccine and COVID-19 vaccine.
- Revaccinate persons who received doses of COVID-19 vaccine prior to or during hematopoietic cell transplantation (HCT) or chimeric antigen receptor T-cell (CAR-T-cell) therapy, following the current COVID-19 vaccination schedule. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy

For more information, please see [CDC’s Interim Clinical Considerations Appendix A](#).

3. Screen for contraindications and precautions

- a. **Contraindications:** History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Pfizer-BioNTech vaccine or to a component of the Pfizer-BioNTech COVID-19 vaccine.
- b. **Precautions:**
 - i. A diagnosed non-severe allergy to a component of the COVID-19 vaccine.
 - ii. Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of COVID-19, if receiving the same vaccine type.
 - iii. Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A).
 - iv. Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.

- v. Moderate to severe illness with or without fever.
 4. Provide information on the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) information statement 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 Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula).
 - ii. As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the [information for recipients and caregivers](#) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) including: **(1)** FDA has approved the use of the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) for ages 12 and older; there is an Emergency Use Authorization in place for ages 5-11. **(2)** The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula); **(3)** The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula), 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.
 - b. **For those aged 5 to 11 years of age:** Provide each patient's legal guardian, as applicable, the package insert, or direct the individual to the website to [obtain the fact sheet for the EUA](#).
 - c. **For those aged 12 years or older:** There is currently no Vaccine Information Sheet (VIS). Once a VIS is available it should be used; but vaccination should not be delayed because of the absence of a VIS. See below for more information on alternative information materials that can be provide. Check for the VIS here: <https://www.cdc.gov/vaccines/hcp/vis/current-vis.html>.
 - d. Obtain consent to administer the vaccine from the patient or the patient's legal guardian, as applicable following the pharmacy's policies for consent.
 - e. Provide necessary information on receiving the next dose of vaccine, if applicable.
5. Prepare to administer vaccine
 - a. Administration of single dose vials and prefilled syringes
 - i. Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) vials do not contain preservatives. Strict adherence of aseptic technique during administration must be followed.
 - ii. **Carefully inspect the vial or pre-filled syringes prior to preparation.** The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) in the single dose vial for individuals 12 and older has a **gray cap** and a label with a **gray border**. The prefilled syringes for ages 12+ have a **gray label border**. The single dose vials for ages 5-11 have a **blue cap and blue label border**.
 - iii. Inspect the vaccine in the vial or pre-filled syringe. Prior to mixing the vial, the thawed vaccine may contain white to off-white opaque amorphous particles. Plastic prefilled syringes and single dose vials may arrive frozen at ultra-cold conditions in thermal containers with dry ice. Once received, frozen plastic prefilled syringes and vials may be immediately transferred to the refrigerator at 2°C to 8°C (35°F to 46°F), thawed and stored for up to 10 weeks. Cartons of 10

single dose plastic prefilled syringes or cartons of 10 single dose vials may take up to 2 hours to thaw at this temperature. Once thawed, they should not be refrozen.

- iv. The glass pre-filled syringe should never be frozen or kept at ultra-low temperature, and therefore does not need to be thawed. If glass pre-filled syringes have been frozen, discard. The total time out of refrigeration (at temperatures between 8°C and 25°C (46°F and 77°F)) must not exceed 12 hours.
- v. Before use, mix the vial by inverting vaccine vial gently 10 times. Do not shake.
- vi. After mixing, the vaccine should appear as an off-white suspension with no visible particles. 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.

b. Administration of single dose syringes

- i. Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) syringes do not contain preservatives. Strict adherence of aseptic technique during administration must be followed.
- ii. Inspect the vaccine in the syringe. The vaccine will be a white to off-white suspension. Do not administer if vaccine is discolored or contains particulate matter.
- iii. Do not shake.
- iv. Remove tip cap and attach a sterile needle.

6. Administer vaccine:

- a. Choose the correct needle gauge, needle length and injection site.
- b. Visually assess patient weight and select a needle for vaccine administration based on the following:

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”

* For administration in the deltoid, 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**).

Administer Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) by intramuscular injection:

5-11 years: 0.3 mL/10ug

12 years of age and older: 0.3 mL/30ug

Administer the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) in the deltoid muscle via the intramuscular (IM) route. Alternately, the anterolateral thigh can be used. A 1.5-inch needle is typically used for adults if administering vaccine in this site. More information about choice of needle length can be found at

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html#t6_2

- i. For vials: 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 (2023-2024 Formula). If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.
- ii. For syringes: Administer the entire volume to deliver a single 0.3 mL dose. For the prefilled syringe, remove tip cap and attach a sterile needle. Do not shake. Administer the entire volume to deliver a single 0.3 mL dose.
- iii. For single dose vials and syringes, discard immediately after use.

7. Document Vaccination

- a. Document each patient's vaccine administration information and follow-up in the following places:
 - i. **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 person administering the vaccine, 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).
 - ii. **Signed Certificate of Immunization** (given to the patient): Record the patient's name, date of vaccination, name/location of the administering pharmacy, administering pharmacist, name of vaccine, manufacturer and lot number, and recommendations for future immunizations.
 - iii. **New York State Immunization Information System (NYSIIS) and City Immunization Registry (CIR):** Report all doses administered to those 18 years of age and younger to NYSIIS or CIR within 24 hours of administration. Report all doses administered to those 19 years of age and older to NYSIIS and CIR after obtaining consent. With respect to NYSIIS, if the dose was documented in CDMS, then the NYSDOH shall transmit data from CDMS to NYSIIS.

8. Management of medical emergencies

- a. A post vaccination observation period should be considered to monitor patients for the occurrence of immediate adverse reactions:
 - 30 minutes:

- History of non-severe, immediate (less than 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
- History of allergy-related contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis after non-COVID-19 vaccines or injectable therapies
- 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. Pharmacists 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:

- i. 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>
- ii. 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>
- iii. Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting” at <https://www.immunize.org/catg.d/p3082.pdf>.
- iv. 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>

9. Reporting of adverse events

- a. Report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) of which they become aware to Vaccine Adverse Events Electronic Reporting System (VAERS) 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 myocarditis or pericarditis after vaccine
 - iv. Cases of Multisystem Inflammatory Syndrome in children and adults
 - v. Cases of COVID-19 that result in hospitalization or death
 - vi. Any additional adverse events and revised safety requirements per the Food and Drug Administration’s conditions for use of an authorized vaccine

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.

b. Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967.

10. Storage and Handling of Vaccine for Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

- a. For storage and handling details, please refer to the fact sheet and package insert:
- i. For ages 5-11: Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula), located here: <https://www.fda.gov/media/167211/download?attachment>
 - ii. For ages 12 and up please see the package insert, located here: Fact Sheet for <https://labeling.pfizer.com/ShowLabeling.aspx?id=16351&format=pdf>

Order: I am hereby prescribing this non patient-specific order to administration of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula). Specifically, pharmacists who are employees, volunteers, or contractors of the pharmacy licensed in New York State may administer Pfizer-BioNTech COVID-19 Vaccine, as permitted by its BLA approval or 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 June 28, 2024 through June 28, 2025. In the event that I discontinue this non patient-specific order prior to June 28, 2025, notice of such discontinuance shall be provided to those employees, volunteers, and contractors of the pharmacy licensed in New York State permitted to execute under this Order using the usual methods of communication.



Signature:

Date: June 28, 2024

Name of Physician: James V. McDonald, M.D., M.P.H.

Title: Commissioner

Institution: New York State Department of Health

NYS License No.: 186383

Effective Date of Order: June 28, 2024