

Non Patient-Specific Standing Order for the Administration of the Moderna Updated COVID-19 Vaccine (2023-2024 Formula) for Persons 3 Years to 4 Years of Age by Pharmacists (Updated 10/18/2023)

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Moderna COVID-19 Vaccine (2023-2024 Formula) vaccination as permitted by the policy and order sections of this Order.

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 standing orders in New York State and who are certified in cardio-pulmonary resuscitation, may administer the Moderna Updated COVID-19 Vaccine (2023-2024 Formula) 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 Moderna 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 “Moderna COVID-19 Vaccine (2023-2024 Formula)” in this standing order.

Moderna 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 Moderna COVID-19 Vaccine (2023-2024 Formula) single dose vials for persons 3 years to 4 years of age administered intramuscularly.

1. Assess children 3 years to 4 years of age *who are NOT moderately to severely immunocompromised* for eligibility for Moderna 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 Moderna COVID-19 (2023-2024 Formula) doses indicated	Dosage	Vaccine vial cap and label border colors	Interval between doses

Unvaccinated	2	0.25 mL/25 ug	Single dose vial with dark blue cap and green label border	Dose 1 Dose 2 at least 4-8 weeks after dose 1
1 previous dose of any Moderna COVID-19 Vaccine	1	0.25 mL/25 ug	Single dose vial with dark blue cap and green label border	Dose 2 at least 4-8 weeks after dose 1.
2 previous doses of any Moderna COVID-19 Vaccine NOT including updated 2023-2024 formula	1	0.25 mL/25ug	Single dose vial with dark blue cap and green label border	Dose 3 at least 8 weeks after Dose 2
2 or more doses of Moderna Vaccine INCLUDING at least 1 dose of 2023-2024 COVID-19 Vaccine	0			No further doses are indicated

Notes:

An 8 week interval between the first and second COVID-19 vaccine might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

People who are recommended to receive a multidose mRNA series for initial vaccination (i.e., children ages 6 month to 4 years and those who are moderately or severely immunocompromised) should receive all doses from the same manufacturer. However, in the following exceptional circumstances a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available, the person would otherwise not complete the vaccination series, or the person starts but is unable to complete a vaccination with the same vaccine due to a contraindication.

Children who have received 1 Moderna and 1 Pfizer-BioNTech vaccines of any formulation need to receive a third dose of either Moderna vaccine or Pfizer-BioNTech vaccine s at least 8 weeks after the second dose.

For more information, please see CDC’s Interim Clinical Considerations:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

2. Assess individuals aged 3 years to 4 years *who are moderately to severely immunocompromised* and administer Moderna COVID-19 Vaccine (2023-2024 Formula) dose(s) according to the table below:

COVID-19 Vaccination history prior to updated	Number of Moderna COVID-19 (2023-2024	Dosage	Vaccine vial cap and label border colors	Interval between doses
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(2023-2024 Formula)	Formula) doses indicated			
Unvaccinated	3	0.25 mL/25ug	Single dose vial with dark blue cap and green label border	Dose 1 Dose 2 at least 4 weeks after dose 1 Dose 3 at least 4 weeks after dose 2
1 previous dose any Moderna COVID-19 Vaccine	2	0.25 mL/25ug	Single dose vial with dark blue cap and green label border	Dose 2 at least 4 weeks after dose 1. Dose 3 at least 4 weeks after dose 2.
2 doses any Moderna COVID-19 Vaccine	1	0.25 mL/25 ug	Single dose vial with dark blue cap and green label border	Dose 3 at least 4 weeks after dose 2
3 or more doses any Moderna COVID-19 Vaccine NOT including at least 1 dose of 2023-2024 COVID-19 vaccine	1	0.25 mL/25 ug	Single dose vial with dark blue cap and green label border	At least 8 weeks after last dose
3 or more doses of Moderna Vaccine, INCLUDING at least one dose of 2023-2024 COVID-19 vaccine	1	0.25 mL/25 ug	Single dose vial with dark blue cap and green label border	-People who are moderately or severely immunocompromised have the option to receive 1 additional dose at least 8 weeks (2 months) following the last recommended dose -Further additional doses may be administered informed by the clinical judgement of a health care provider and personal preference and circumstances -Any further additional doses should be administered at least 8 weeks (2 months) after the last COVID-19 vaccine dose

Notes:

People who are recommended to receive a multidose mRNA series for initial vaccination (i.e., children ages 6 month to 4 years and those who are moderately or severely immunocompromised) should receive all doses from the same manufacturer. However, in the following exceptional circumstances a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available, the person would otherwise not complete

the vaccination series, or the person starts but is unable to complete a vaccination with the same vaccine due to a contraindication.

Children who have received 1 Moderna and 1 Pfizer-BioNTech vaccines of any formulation need to receive a third dose of either Moderna vaccine or Pfizer-BioNTech vaccine s at least 8 weeks after the second dose.

Additional Clinical Considerations

- Moderna COVID-19 Vaccine (2023-2024 Formula) may be simultaneously administered with other routinely recommended vaccines.
- 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:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

3. Screen for contraindications and precautions

a. **Contraindications:** History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Moderna vaccine to a component of the Moderna 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. Moderate to severe acute illness, with or without fever
- iv. Multisystem inflammatory syndrome in children (MIS-C).
- v. Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.

4. Provide information on the Moderna COVID-19 Vaccine (2023-2024 Formula) 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 Moderna 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 Moderna COVID-19 Vaccine (2023-2024 Formula) including: (1) FDA has approved the use of the Moderna COVID-

19 Vaccine (2023-2024 Formula) for ages 12 and older; there is an Emergency Use Authorization in place for ages 6 months-11 years. **(2)** The recipient or their caregiver has the option to accept or refuse Moderna COVID-19 Vaccine (2023-2024 Formula); **(3)** The significant known and potential risks and benefits of Moderna 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 3 years to 4 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. Obtain consent to administer the vaccine from the patient or the patient's legal guardian as applicable following the pharmacy's policies for consent.
- d. Provide necessary information on receiving the next dose of vaccine, if applicable.

5. Prepare to administer vaccine

- a. Administration of single dose vials
 - i. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.25 mL of the Moderna COVID-19 Vaccine (2023-2024 Formula). If the amount of vaccine remaining in the vial cannot provide a full dose of 0.25 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.
 - ii. Moderna COVID-19 Vaccine single dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
 - iii. Swirl vial gently after thawing. Do not shake. Do not dilute the vaccine.
 - iv. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
 - v. Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.

Each single dose vial contains one dose of 0.25 mL for ages 6 months through 4 years. Each vial is single use only. Discard after single use.

6. Administer vaccine:

- i. For children 3 through 4 years of age, use a 22-25 gauge, 1 inch needle. Give the vaccination in the deltoid muscle in the upper arm.
- ii. Administer Moderna COVID-19 Vaccine (2023-2024 Formula) by intramuscular injection, 0.25mL/25ug.
 - a. For vials: Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.25 mL of the Moderna COVID-19 Vaccine (2023-2024 Formula). If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.
 - b. For single dose vials, discard immediately after use.

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 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).

Signed Certificate of Immunization (given to the patient's parent or legal guardian): Record the patient's name, date of vaccination, name/location of the administering pharmacy, administering pharmacist (name or signature), 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 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 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 appropriate for age, 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>

9. Reporting of adverse events

- a. Report the following information associated with the administration of Moderna 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.

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

10. Storage and Handling of Vaccine for Moderna COVID-19 Vaccine (2023-2024 Formula)
 - a. Storage of Single Dose Vials Prior to Use
 - i. Moderna COVID-19 vaccines (2023-2024 Formula) contain preservative-free frozen suspension that must be stored at appropriate temperatures to preserve efficacy. Consult CDC, NYSDOH and Moderna guidance on storage and handling of Moderna COVID-19 vaccines.
 - ii. Moderna COVID-19 vaccine single dose vials received frozen may be stored in a standard freezer between -50°C to -15°C (-58F to 5° F) until expiration date.
 - iii. Unpunctured vials can be stored in the refrigerator between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use, not to exceed the expiration date. The 30-day refrigerated expiry date should be recorded on the carton at the time of transfer.
 - iv. Once thawed, unpunctured vials should not be refrozen. If vaccine is received thawed, it must be stored in the refrigerator between 2°C to 8°C (36°F to 46°F).
 - v. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
 - b. Thawing and Storage of Single Dose Vials During Use
 - i. Thaw between 2°C to 8°C (35°F to 46°F) for 45 minutes. Let each vial stand at room temperature for 15 minutes before administering.
 - ii. Alternatively, thaw at room temperature [15°C to 25°C (59°F to 77°F)] for 15 minutes.
 - iii. Thawed vials can be handled in room light conditions.
 - iv. Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours.
 - v. Vials should be discarded after single use.
 - vi. Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.

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

Signature:  _____

Date: 10/19/23

Name of Physician: James V. McDonald, MD, MPH

Title: Commissioner of Health

Institution: New York State Department of Health

NYS License No.: 186383

Effective Date of Order: October 19, 2023