NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

Non Patient-Specific Standing Order for the Administration of the Moderna Updated COVID-19 Vaccine (2024-2025 Formula)
For Persons 3 Years to 4 Years of Age
by Pharmacists
(Updated 09/17/2024)

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Moderna COVID-19 Vaccine (2024-2025 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 standing orders in New York State and who are certified in cardio-pulmonary resuscitation, may administer the Moderna Updated COVID-19 Vaccine (2024-2025 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 2024–2025 Moderna formulation has been updated as a monovalent vaccine based on the Omicron KP.2 strain of SARS-CoV-2 and will be referred to as the "Moderna COVID-19 Vaccine (2024-2025 Formula)" in this standing order. For ages 3 through 4 years, the product comes in pre-filled single-dose syringes.

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 (2024-2025 Formula) single dose, pre-filled syringes 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 (2024-2025 Formula) based on the following criteria and administer dose(s) according to the table below:

COVID-19 Vaccination history	Number of Moderna COVID-19 (2024-2025 Formula) doses indicated	Dosage (mL/ug)	Interval between doses
Unvaccinated	2	0.25 mL/25 ug	**Dose 1**: Day 0 **Dose 2**: 4-8 weeks after Dose 1*
1 previous dose of any Moderna COVID-19 Vaccine	1	0.25 mL/25 ug	**Dose 2**: 4-8 weeks after Dose 1*
2 previous doses of any Moderna COVID-19 Vaccine NOT including at least 1 dose 2024-2025 Moderna	1	0.25 mL/25ug	At least 8 weeks after last dose
2 or more doses of Moderna Vaccine INCLUDING at least 1 dose of 2024-2025 COVID-19 Vaccine	No further doses are indicated		

*An 8-week interval between the first and second COVID-19 vaccine (Moderna and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

2. Assess individuals aged 3 years to 4 years *who are moderately to severely immunocompromised* and administer Moderna COVID-19 Vaccine (2024-2025 Formula) dose(s) according to the table below:

COVID-19 Vaccination history	Number of Moderna COVID-19 (2024-2025 Formula) doses indicated	Dosage (mL/ug)	Interval between doses

Unvaccinated	3	0.25 mL/25ug	**Dose 1**: Day 0 **Dose 2**: 4 weeks after Dose 1 **Dose 3**: At least 4 weeks after Dose 2 **See additional doses**
1 dose any Moderna COVID-19 Vaccine	2	0.25 mL/25ug	**Dose 2**: 4 weeks after Dose 1 **Dose 3**: at least 4 weeks after Dose 2 **See additional doses**
2 doses any Moderna COVID-19 Vaccine	1	0.25 mL/25 ug	**Dose 3**: At least 4 weeks after Dose 2 **See additional doses**
3 or more doses any Moderna COVID-19 Vaccine NOT including at least 1 dose of 2024-2025 Moderna COVID-19 vaccine	1	0.25 mL/25 ug	At least 8 weeks after last dose **See additional doses**
3 or more doses any Moderna Vaccine, INCLUDING at least 1 dose of 2024-2025 COVID-19 vaccine	**See additional doses**		
ADDITIONAL DOSES: Children in this age group may receive 1 additional dose of 2024–2025 mRNA COVID-19 vaccine from the same manufacturer as the initial series at least 2 months after the last 2024–2025 mRNA vaccine dose indicated in the table. Further additional 2024–2025 mRNA dose(s) may be administered from the same manufacturer, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last 2024–2025 mRNA vaccine dose.			

Additional Clinical Considerations

- Moderna COVID-19 Vaccine (2024-2025 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.
- Administration of COVID-19 vaccines should not be delayed in patients taking immunosuppressive therapies. Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies. For patients who receive B-cell-depleting therapies on a continuing basis, COVID-19 vaccines should be administered approximately 4 weeks before the next scheduled therapy.

- 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 additional details and all clinical considerations, see Interim Clinical Considerations for Use of COVID-19 Vaccines

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 (2024-2025 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 (2024-2025 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 (2024-2025 Formula) including: **(1)** FDA has approved the use of the Moderna COVID-19 Vaccine (2024-2025 Formula) for ages 12 and older; there is an Emergency Use Authorization in place for ages 6 months-11years. **(2)** The recipient or their caregiver has the option to accept or refuse Moderna COVID-19 Vaccine (2024-2025 Formula); **(3)** The significant known and potential risks and benefits of Moderna COVID-19 Vaccine (2024-2025 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 written instructions to the parent or legal guardian regarding appropriate course of action in the event of adverse reactions.
e. Provide necessary information on receiving the next dose of vaccine, if applicable.

5. Administer vaccine:
   a. 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.
   b. Administer Moderna COVID-19 Vaccine (2024-2025 Formula) by intramuscular injection, 0.25mL/25ug and discard immediately after use.

6. 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 14 days hours of administration. With respect to NYSIIS, if the dose was documented in the Countermeasure Data Management System (CDMS), then the NYSDOH shall transmit data from CDMS to NYSIIS for all patients ages 18 and younger and for those who are 19 and older, with consent

7. 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 Children and Teens in a Community Setting" at https://www.immunize.org/catg.d/p3082a.pdf

8. Reporting of adverse events
    a. Report the following information associated with the administration of Moderna COVID-19 Vaccine (2024-2025 Formula) 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 myocarditis or pericarditis after 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.

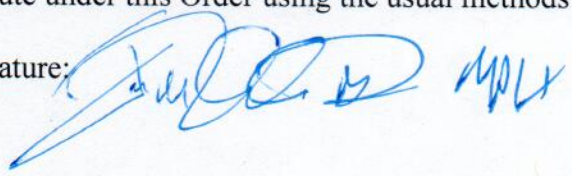
iv. Cases of Multisystem Inflammatory Syndrome in children and adults
v. Cases of COVID-19 that result in hospitalization or death
vi. Any additional adverse events and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine

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

9. Storage and Handling of Vaccine for Moderna COVID-19 Vaccine (2023-2024 Formula)
   a. For storage and handling details, please refer to the Fact Sheet for Healthcare Providers located here: https://www.fda.gov/media/167208/download?attachment

Order: I am hereby prescribing this non patient-specific order to administration of Moderna COVID-19 Vaccine (2024-2025 Formula). 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 September 19, 2024 through December 31, 2024. In the event that I discontinue this non patient-specific order prior to December 31, 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: September 19, 2024

Name of Physician: James V. McDonald MD MPH

Title: Commissioner

Institution: New York State Department of Health

NYS License No.: 186383

Effective Date of Order: September 19, 2024

Medicaid No: 07693570

NPI: 1619966959