



**Non-Patient Specific Standing Order for the Administration of the
Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula)
for Persons 12 Years of Age and Older by Pharmacists
(Updated 9/12/2025)**

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula) 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 (NYS) and who are certified in cardio-pulmonary resuscitation may administer the Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula) to eligible individuals, as permitted by its Biologics License Application (BLA) approval or Emergency Use Authorization (if 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 2025–2026 Moderna mNEXSPIKE formulation has been updated to a monovalent vaccine based on the Omicron variant sublineage LP.8.1 and will be referred to as the “Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula)” in this standing order. It has full Biologics License Application approval under the brand name “mNEXSPIKE.” The product has Biologics License Application approval for use in the following individuals:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19 (see Table 1 for complete list)
- Those who self-attest to their moderately or severely immunocompromised status, even without documentation

NOTE: Pharmacists must follow the requirements set forth in 8 NYCRR sections 63.9 & 64.7 respectively, including providing patients with requisite information, maintaining adequate records and adhering to reporting requirements.

Procedure: This standing order is for use of Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula) prefilled, single-dose syringes for persons 12 years and older administered intramuscularly and a single dose is 0.2 mL.

1. Assess individuals ages 12 years of age and older who are *not immunocompromised* irrespective of previous COVID-19 vaccination status per table below:

Age	Number of mNEXSPIKE COVID-19 2025-2026 doses indicated	Dosage
12 years and older	1	0.20 mL
If previously vaccinated with any COVID-19 vaccine, administer the dose ≥ 3 months after the last dose of COVID-19 vaccine.		

2. Assess individuals ages 12 years of age and older who *are immunocompromised* for COVID-19 vaccination status per table below:

COVID-19 Vaccination history before 2025-2026 vaccine [^]	Number of mNEXSPIKE COVID-19 2025-2026 doses indicated	Dosage	Interval between doses
Unvaccinated	4	0.20 mL	<p>2025-2026 Dose 1: Day 0</p> <p>2025-2026 Dose 2: 4 weeks after Dose 1</p> <p>2025-2026 Dose 3: 4 weeks after Dose 2</p> <p>2025-2026 Dose 4: At least six months (minimum interval 2 months) after Dose 3*</p>
Previous 1 dose Moderna	3	0.20 mL	<p>2025-2026 Dose 1: 4 weeks after previous dose</p> <p>2025-2026 Dose 2: At least 4 weeks after 2025 – 2026 Dose 1</p> <p>2025-2026 Dose 3:</p>

			At least six months (minimum interval 2 months) after 2025 – 2026 Dose 2*
Previous 2 doses of Moderna	2	0.20 mL	2025-2026 Dose 1: At least 4 weeks after previous Moderna dose 2025-2026 Dose 2: At least six months (minimum interval 2 months) after 2025-2026 Dose 1*
Previously completed initial 3-dose vaccination series with 3 or more doses Moderna or Pfizer or Novavax	2	0.20 mL	2025-2026 Dose 1: Administer at least 8 weeks after previous dose 2025-2026 Dose 2: At least six months (minimum interval 2 months) after 2025-2026 Dose 1*

^ COVID-19 vaccination history refers to all doses of COVID-19 vaccine from Pfizer or Moderna received before the availability of the 2025-2026 COVID-19 vaccines

* Providers may administer further additional doses based on clinical judgment, patient circumstance, and product specific standing order.

Additional Clinical Considerations

- Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 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.

3. Screen for contraindications and precautions

- a. **Contraindications:** History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of mNEXSPIKE or after a previous Moderna COVID-19 vaccine dose.

- 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. History of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A).
 - iv. History of 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 COVID-19 Vaccine 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 Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 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 mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula) including: **(1)** FDA has approved the use of the Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula) for ages 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19 and approved the use in persons ages 65 years of age and older, or **(2)** The recipient or their caregiver has the option to accept or refuse Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula); **(3)** The significant known and potential risks and benefits of Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 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. Provide each patient or patient’s legal guardian, as applicable with the Vaccine Information Statement located here: https://www.cdc.gov/vaccines/hcp/current-vis/covid-19.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/vis/vis-statements/covid-19.html
 - 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. Prepare to administer vaccine
- a. Administration of single dose, prefilled syringes for individuals aged 12 and above:
 - i. Verify that the label on the prefilled syringe states 2025-2026 Formula.

- ii. If prefilled syringes of mNEXSPIKE are frozen, thaw before use according to the table below:

	Thaw in Refrigerator 2°C to 8°C (36°F to 46°F)	Thaw at Room Temperature 15°C to 25°C (59°F to 77°F)
Carton of 10 syringes	Thaw for 2 hours and 40 minutes	Thaw for 1 hour and 20 minutes
Carton of 2 syringes	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes
Carton of 1 syringe	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes
One syringe (removed from carton)	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes

- iii. After thawing, do not refreeze.
- iv. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- v. mNEXSPIKE 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.
- vi. Do not shake.
- vii. With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases.
- viii. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.

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 Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula) by intramuscular injection:

12 years of age and older: 0.20 mL

Administer the Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 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

7. Document vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical Record System (including Countermeasure Data Management System [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 § 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 pharmacist, 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 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 must transmit data from CDMS to NYSIIS for all patients ages 18 and younger and for those who are 19 and older, with consent.

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 sufficient epinephrine to administer 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/imz-best-practices/preventing-managing-adverse-reactions.html>
- 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 any vaccine adverse events to the US Department of Health and Human Services. Visit <https://vaers.hhs.gov/> to file a report or call 1-800-822-7967.
- b. Conduct any follow-up requested by the U.S government, including the Centers for Disease Control and Prevention, the Food and Drug Administration, or other designee, regarding adverse events to the extent feasible given the emergency circumstances

10. Storage and Handling of Vaccine for Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula)

- a. For storage and handling details, please refer to the fact sheet and package insert: <https://www.fda.gov/media/186738/download?attachment>

Order: I am hereby prescribing this non-patient specific order for administration of Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula). Specifically, pharmacists who are employees, volunteers, or contractors of a pharmacy licensed in New York State may administer Moderna mNEXSPIKE COVID-19 Vaccine (2025-2026 Formula), as permitted by its Biologics License Application approval or Emergency Use Authorization (if applicable) by the U.S. Food and Drug Administration, state or federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness Act declarations, or the recommendations of the Advisory Committee on Immunization Practices.

This non-patient specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on September 12, 2025 through September 11, 2026. In the event that I discontinue this non-patient specific order prior to September 11, 2026, 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: September 12, 2025

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

Title: Commissioner

Institution: New York State Department of Health

NYS License No.: 186383

Medicaid No: 076963570

NPI: 1619966959

Effective Date of Order: September 12, 2025

Table 1: CDC 2025 List of Underlying Medical Conditions That Increase a Person's Risk of Severe COVID-19 †
Asthma
Cancer <ul style="list-style-type: none"> ▪ Hematologic malignancies
Cerebrovascular disease
Chronic kidney disease* <ul style="list-style-type: none"> ▪ People receiving dialysis^
Chronic lung diseases limited to the following: <ul style="list-style-type: none"> ▪ Bronchiectasis ▪ COPD (chronic obstructive pulmonary disease) ▪ Interstitial lung disease ▪ Pulmonary embolism ▪ Pulmonary hypertension
Chronic liver disease limited to the following: <ul style="list-style-type: none"> ▪ Cirrhosis ▪ Nonalcoholic fatty liver disease ▪ Alcoholic liver disease ▪ Autoimmune hepatitis
Cystic Fibrosis

Children with certain underlying conditions §
Diabetes mellitus, type 1
Diabetes mellitus, type 2*
Disabilities ‡, including Down's syndrome
Epilepsy
Hemophilia
Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
HIV (human immunodeficiency virus)
Mental health conditions limited to the following: <ul style="list-style-type: none"> ▪ Mood disorders, including depression ▪ Schizophrenia spectrum disorders
Neurologic conditions limited to dementia ‡ and Parkinson's disease
Obesity (BMI ≥30 or ≥95 th percentile in children)
Overweight (BMI ≥25 kg/m ² but <30kg/m ²)
Physical inactivity
Pregnancy and recent pregnancy
Primary immunodeficiencies
Sickle cell disease
Smoking, current and former
Substance use disorders
Solid-organ or blood stem-cell transplantation
Tuberculosis
Use of corticosteroids or other immunosuppressive medications

* Indicates presence of evidence for pregnant and nonpregnant women.

^ Risk may be further increased for people receiving dialysis

§ Information for Pediatric Healthcare Providers (<https://www.cdc.gov/covid/hcp/clinical-care/for-pediatric-hcp.html>)

‡ Underlying conditions for which there is evidence in pediatric patients.

¥ Centers for Disease Control and Prevention. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19. CDC. Published June 11, 2025. Accessed September 4, 2025. <https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html>. This resource provides detailed evidence grading for each clinical condition listed in the table.