NEW YORK STATE OF OPPORTUNITY. Department of Health

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Non Patient-Specific Standing Order for the Administration of the Novavax COVID-19 Vaccine (2023-2024 Formula), for persons 12 years of age and older by Pharmacists
(Updated 11/07/2023)

Purpose: To reduce morbidity and mortality from COVID-19 by administering the Novavax COVID-19 Vaccine (2023-2024 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 orders in New York State and who are certified in cardio-pulmonary resuscitation, may administer the Novavax COVID-19 Vaccine (2023-2024 Formula), to individuals ages 12 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 Novavax formulation has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2 and will be referred to as the "Novavax COVID-19 Vaccine (2023-2024 Formula)" in this standing order.

Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) 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 Novavax COVID-19 Vaccine (2023-2024 Formula) single dose vials for persons 12 years and older administered intramuscularly.

1. Assess individuals ages 12 years and above who *are NOT moderately to severely immunocompromised* for eligibility for Novavax 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 Novavax (2023-2024 Formula)	Dosage	Vaccine vial cap and label colors	Interval between doses

	doses indicated			
Unvaccinated	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label border	Dose 1 and Dose 2: 3-8 weeks*
1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine dose**	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label border	At least 8 weeks after last dose

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

**If an individual has previously received ONLY original monovalent or bivalent mRNA dose(s), please refer to the standing order for the updated (2023-2024) mRNA COVID-19 vaccines. It is not recommended to use the Novavax vaccine in this instance, but instead recommend completing the series using the mRNA vaccine from the same manufacturer as the product of which the individual has already received 1 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 12 years and older who *are moderately to severely immunocompromised* and administer Novavax COVID-19 Vaccine (2023-2024 Formula) according to the table below:

COVID-19 Vaccination history prior to updated (2023-2024 Formula)	Number of Novavax COVID-19 (2023-2024 Formula) doses indicated	Dosage	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label border	Dose 1 and Dose 2: 3 weeks
1 or more doses Novavax or	1	0.5 mL/50ug or 0.25mL/25ug	Blue cap; blue label border	At least 8 weeks after last dose

Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine dose**				

** If an individual has previously received ONLY original monovalent or bivalent mRNA dose(s), please refer to the standing order for the updated (2023-2024) mRNA COVID-19 vaccines. It is not recommended to use the Novavax vaccine in this instance, but instead recommend completing the series using the mRNA vaccine from the same manufacturer as the product of which the individual has already received 1 dose.

Note: People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose Novavax COVID-19 Vaccine (2023-2024 Formula) dose at least 2 months following the last recommended updated (2023-2024 Formula) vaccine dose. 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.

Additional Clinical Considerations

- Novavax 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: 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 Novavax COVID-19 vaccine or to a component of the Novavax 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 Novavax 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 Novavax 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 Novavax COVID-19 Vaccine (2023-2024 Formula) including: **(1)** FDA has issued an Emergency Use Authorization for use of the Novavax COVID-19 Vaccine (2023-2024 Formula). **(2)** The recipient or their caregiver has the option to accept or refuse Novavax COVID-19 Vaccine (2023-2024 Formula); **(3)** The significant known and potential risks and benefits of Novavax 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.
   iii. Obtain consent to administer the vaccine from the patient or the patient's legal guardian, as applicable. [Insert how the Organization will be documenting consent and what forms will be used].
   iv. Provide the Fact Sheet for Recipients and Caregivers, located here: https://www.fda.gov/media/159898/download?attachment
   v. Provide necessary information on receiving the next dose of vaccine, if applicable.

5. Prepare to administer vaccine

a. Novavax COVID-19 Vaccine, Adjuvanted is available as multi-dose vials containing 5 doses of 0.5 mL each.
b. Novavax COVID-19 vaccine vials do not contain preservatives. Strict adherence of aseptic technique during administration must be followed.
c. Swirl vial gently between each withdrawal. Do not shake. Do not dilute the vaccine.
d. Inspect the liquid in the vial. The liquid is a colorless to slightly yellow, clear to mildly opalescent suspension, free from visible particles.

e. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer the vaccine if either of these conditions exist. 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**).

f. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw the correct volume for the dose being administered: 0.5mL
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 Novavax COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not freeze. Do not withdraw more than 5 doses from a single vial.

6. Administer vaccine:

a. Choose the correct needle gauge, needle length and injection site.
b. Administer Novavax COVID-19 Vaccine (2023-2024 Formula) by intramuscular injection: 0.5mL

Administer the Novavax 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

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)**:** Record the patient’s name, date of vaccination, name/location of the administering pharmacy, administering pharmacist (can be a signature or printed name), 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 an 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, particularly when vaccinating adolescents

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:

- 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 Novavax 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)
        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 approval

    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 Novavax COVID-19 Vaccine (2023-2024 Formula)

    a. The Novavax COVID-19 Vaccine multi-dose vial does not contain a preservative. Consult CDC, NYSDOH and Novavax guidance on storage and handling of Novavax COVID-19 vaccines.
    b. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
    c. Store the unpunctured multi-dose vial in a refrigerator between 2° to 8°C (36° to 46°F) until the expiration date.
    d. **Do not freeze**.
    e. After the first needle puncture, store the vial between 2° to 25°C (36° to 77°F) for up to 12 hours. Mark the date and time of first puncture on the vial label. Discard the vial 12 hours after the first puncture.
    f. Do not use the vaccine after the expiration date verified by the online expiration tool at Novavax Vaccine Fact Sheet & Resources | Novavax Vaccine (novavaxcovidvaccine.com)

Order: I am hereby prescribing this non patient-specific order to administration of Novavax COVID-19 Vaccine (2023-2024 Formula). Specifically, pharmacists who are employees, volunteers, or contractors of the pharmacy licensed in New York State may administer Novavax

COVID-19 Vaccine, as permitted by its Biologics License Application (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 11/13/2023 through 11/13/2024. In the event that I discontinue this non patient-specific order prior to 11/13/2024, 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: 11/13/2023

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: __11/13/2023
Medicaid No: 07693570