# Novavax (2023-2024) COVID-19 Vaccine, Adjuvanted Protocol

vaccine protocol for Persons Age 12 years and older

**Document reviewed and updated:** **March 18, 2024**

## Condition for protocol

To reduce incidence of morbidity and mortality of COVID-19 disease.

## Policy of protocol

The nurse will implement this protocol for COVID-19 vaccination using the Novavax (2023-2024) COVID-19 vaccine, adjuvanted for persons 12 years and older.

## Condition-specific criteria and prescribed actions

**Delete this entire paragraph before printing/signing protocol.**

[Instructions for persons adopting these protocols: The table below lists indication, contraindication, and precaution criteria and suggested prescribed actions that are necessary to implement the vaccine protocol. The prescribed actions include examples shown in brackets but may not suit your institution’s clinical situation and may not include all possible actions. A licensed prescriber must review the criteria and actions and determine the appropriate prescribing action.]

Indications

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Person is currently healthy and age 12 years or older. | Proceed to vaccinate if meets remaining criteria. |
| Person is less than age 12 years.  | Do not administer Novavax vaccine.  If available, vaccinate using FDA-authorized vaccine for persons younger than 12 years using the respective protocol. OR Assist person in finding a vaccination clinic that provides a product licensed for persons younger than 12 years.   |
| Person is currently healthy but has a chronic medical condition.   | Proceed to vaccinate.  |
| Person with HIV infection, other immunocompromising conditions, or who takes immunosuppressive medications or therapies.  | Proceed to vaccinate. Counsel the individual about: 1) The potential for reduced immune responses. 2) The need to continue to follow current guidance to protect themselves.  |
| Person who falls into one of following categories of moderate to severe immunocompromise:* Active treatment for solid tumor and hematologic malignancies.
* Receipt of solid-organ transplant and taking immunosuppressive therapy.
* Receipt of CAR-T-cell or hematopoietic stem cell transplant (within two years of transplantation or taking immunosuppression therapy).
* Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
* Advanced or untreated HIV infection.

Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory. | Proceed to vaccinate using schedule for people with immunocompromising conditions.[Refer to primary care provider if additional doses may be indicated]. |
| Person is pregnant.  | Proceed to vaccinate.  |
| Person is lactating.  | Proceed to vaccinate.  |

Contraindications

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| --- | --- |
| Criteria | Prescribed action |
| Person had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of Novavax vaccine or any of its components. *See listing below the prescription.*  | Do not vaccinate.  |

Precautions

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Person has a moderate to severe illness defined as temperature \_\_\_\_°F/°C or higher with symptoms such as: {to be determined by medical prescriber} | Defer vaccination and {to be determined by medical prescriber}.  |
| Person had a non-severe immediate (within 4 hours) allergic reaction to a previous dose of any COVID-19 vaccine. | The person may be vaccinated but should seek counsel from an allergist-immunologist to discuss risks and benefits of vaccination. Persons who choose vaccination should be observed for 30 minutes in a vaccination site that has equipment and personnel that is familiar with managing anaphylaxis.  |
| Person has a history of myocarditis or pericarditis after a previous dose of COVID-19 vaccine.  | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks.  |
| Person had a delayed local allergic reaction (e.g., erythema, induration, pruritis at the injection site).  | Proceed to vaccinate. Give vaccine in the opposite arm from where the first dose was given.  |
| Person was previous ill with COVID-19 and had Multisystem Inflammatory Syndrome.  | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks.  |

## Prescription

### Persons previously vaccinated with any COVID-19 vaccine:

* Give one dose 2023-2024 Novavax COVID-19 vaccine, adjuvanted; 5 micrograms, 0.5 mL, intramuscular (IM) at least 2 months following any previous COVID-19 dose.

### Persons 65 years and older previously vaccinated with the 2023-2024 COVID-19 vaccine:

* Give one additional dose of 2023-2024 Novavax COVID-19 vaccine, adjuvanted; 5 micrograms, 0.5 mL, intramuscular (IM) at least 4 months following any previous 2023-2024 COVID-19 dose.

### Persons not previously vaccinated with any COVID-19 vaccine:

* Give 2023-2024 Novavax COVID-19 vaccine, adjuvanted; 5 micrograms, 0.5 mL, intramuscular (IM); and give a second dose 3 - 8 weeks following the first dose.

### Immunocompromised individuals:

* Previously unvaccinated: Give 2023-2024 Novavax COVID-19 vaccine, adjuvanted; 5 micrograms, 0.5 mL, intramuscular (IM); and give a second dose 3 weeks following the first dose.
* An additional dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at least 2 months following the last dose of a COVID-19 vaccine.
* Additional doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at the discretion of the healthcare provider, taking into consideration the individual’s clinical circumstances. The timing of the additional doses may be based on the individual’s clinical circumstances.

## Medical emergency or anaphylaxis

Follow pre-established agency protocol for anaphylaxis.

## Question or concerns

**Insert overseeing medical consultant’s information below and delete this sentence before printing/signing.**

In the event of questions or concerns call (insert name) at (insert phone number).

**This protocol shall remain in effect until rescinded.**

Name of prescriber (please print):

Prescriber signature:

Date:

## Ingredient listing for 2023-2024 Novavax COVID-19 vaccine

* 5 mcg of SARS-CoV-2 Omicron variant lineage XBB.1.5 recombinant spike (rS) protein
* 50 mcg Matrix-M adjuvant composed of Fraction-A (42.5 mcg) and Fraction-C (7.5 mcg) of saponin extracts from the soapbark tree, Quillaja saponaria Molina,
* 3.85 mcg cholesterol, phosphatidylcholine, potassium dihydrogen phosphate,
* 2.25 mcg potassium chloride,
* 14.7 mcg disodium hydrogen phosphate dihydrate,
* 2.465 mg disodium hydrogen phosphate heptahydrate,
* 0.445 mg sodium dihydrogen phosphate monohydrate,
* 8.766 mg sodium chloride and
* 0.050 mg polysorbate 80
* Each 0.5 mL dose of the Novavax COVID-19 Vaccine, Adjuvanted may also contain residual amounts of baculovirus and Sf9 cell proteins (≤ 0.96 mcg), baculovirus and cellular DNA (≤ 0.00016 mcg), lentil lectin (< 0.025 mcg), methyl-α-D-mannopyranoside (2 mcg), simethicone (< 2.19 mcg), Triton X-100 (< 0.025 mcg), and Tergitol (NP9) (< 0.05 mcg).
* The vial stoppers are not made with natural rubber latex.

Taken from the *FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION MODERNA COVID-19 VACCINE* found in [Novavax HCP Fact Sheet (www.fda.gov/media/159897/download)](https://www.fda.gov/media/159897/download).