12 Years of Age and Older

2024-2025 Novavax COVID-19 Vaccine

Standing Orders for Administering Vaccine

2024–25 Novavax COVID-19 Vaccine	Age	Dose/Injection Amount	Route
Manufacturer-filled syringe	12 years and older	0.5 mL/5 *µg* rS and 50 µg of Matrix-M™ adjuvant	Intramuscular (IM) injection

Purpose

To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 12 years of age and older for vaccination with the 2024–25 Novavax COVID-19 Vaccine based on the following criteria:

People who are NOT moderately or severely immunocompromised[*]

COVID-19 vaccination history is:	Administer:
Unvaccinated	Give a 2-dose initial series. Administer: ▪ Dose 1 now. ▪ Dose 2 at least 3–8 weeks after Dose 1[†]
1 dose of any Novavax COVID-19 Vaccine (Dose 1)	Complete series. Administer: ▪ Dose 2 at least 3-8 weeks after Dose 1 [†‡]
Any number of previous doses COVID-19 vaccine, **NOT** including at least 1 dose of 2024–25 COVID-19 vaccine	Give 1 dose at least 8 weeks after the previous dose
Any number of previous doses COVID-19 vaccine, **INCLUDING** at least 1 dose of 2024–25 COVID-19 vaccine[§]	No further doses indicated.

* People with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).
† An 8-week interval between the first and second Novavax COVID-19 Vaccine doses might be optimal for some people, as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.
‡ If more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.
§ If the immunization history is only 1 dose of 2024–25 Novavax COVID-19 Vaccine (Dose 1), administer 1 dose of 2024–25 Novavax Vaccine (Dose 2) at least 3-8 weeks after Dose 1.An 8-week interval between the first and second Novavax COVID-19 Vaccine doses might be optimal for some people, as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

People who ARE moderately or severely immunocompromised

COVID-19 vaccination history is:	Administer:*
Unvaccinated	Give 2-dose initial series. Administer:† ▪ Dose 1 now. ▪ Dose 2 at least 3 weeks after Dose 1
1 dose of any Novavax COVID-19 Vaccine (Dose 1)	Complete series. Administer:† ▪ Dose 2 at least 3 weeks after Dose 1.
2 or more doses of any Novavax COVID-19 Vaccine, **NOT** including at least 1 dose of any 2024-25 COVID-19 vaccine	Give 1 dose at least 8 weeks after the previous dose.†
2 or more doses of Novavax COVID-19 Vaccine, **INCLUDING** at least 1 dose of any 2024-25 COVID-19 vaccine	▪ People who are moderately or severely immunocompromised may receive 1 additional dose at least 8 weeks following the last recommended dose. ▪ Further additional dose(s) may be administered, informed by the clinical judgment of a health care provider and personal preference and circumstances. ▪ Any further additional doses should be administered at least 8 weeks after the last COVID-19 vaccine dose.
3 or more doses of any mRNA COVID-19 vaccine, **NOT** including at least 1 one dose of any 2024–25 COVID-19 vaccine	Give 1 dose at least 8 weeks after the previous dose.
3 or more doses of any mRNA COVID-19 vaccine, **INCLUDING** at least 1 dose of any 2024–25 COVID-19 vaccine	▪ People who are moderately or severely immunocompromised may receive 1 additional dose at least 8 weeks following the last recommended dose. ▪ Further additional dose(s) 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 after the last COVID-19 vaccine dose

* People who are moderately or severely immunocompromised should receive the same vaccine product to complete the initial series.
† In the following circumstances, a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available at the time of the clinic visit, the previous dose is unknown, the person would otherwise not receive a recommended dose, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication. Refer to Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC for detailed guidance.

Additional clinical considerations

- 2024–25 Novavax COVID-19 Vaccine may be simultaneously administered with other routinely recommended vaccines. There are additional considerations for simultaneous administration of an orthopoxvirus vaccine and COVID-19 vaccine.
- People who have received hematopoetic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy:
  - Revaccinate people who received doses of COVID-19 vaccine prior to or during HCT or CAR-T-cell therapy, following the current COVID-19 vaccination schedule.
  - Revaccination should start at least 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.

Contraindications:

A severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of Novavax COVID-19 vaccine

Precautions:

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Administration:

- Provide all recipients and/or parents/legal guardians with a copy of the current Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine following the manufacturer's guidance.
  - EUA Fact Sheet for Novavax Vaccine
- Choose the correct needle gauge, needle length, and injection site for persons:
  - **12 through 18 years of age:**
    - Needle gauge/length: 22–25 gauge, 5/8* -1-inch
    - Site: Deltoid muscle of arm†
  - **19 years of age and older:** See chart below.
- Administer **0.5 mL/5 *µg* rS and 50 µg of Matrix-M adjuvant** of Novavax COVID-19 Vaccine by intramuscular (IM) injection.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site†
Female or male less than 130 lbs	22–25	5/8‡–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1.5"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1.5"	Deltoid muscle of arm
Female 200+ lbs	22–25	1.5"	Deltoid muscle of arm
Male 260+ lbs	22–25	1.5"	Deltoid muscle of arm

* A 5/8-inch needle can be used if the skin is stretched tightly, and subcutaneous tissues are not bunched.
† Alternately, the anterolateral thigh can be used. A 1- or 1.5-inch needle may be used if administering vaccine in this site, depending on the age of the patient.
‡ Some experts recommend a 5/8-inch needle for men and women who weigh less than 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).

Document Vaccination

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine.
- **Vaccination record for recipient:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional.
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Be Prepared to Manage Medical Emergencies

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- **30 minutes for persons with:**
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of Novavax COVID-19 vaccine
  - A history of a diagnosed non-severe allergy to a component of Novavax COVID-19 vaccine
- **15 minutes:** All other persons

Syncope may occur in association with injectable vaccines. Procedures should be in place to avoid falling injuries and manage syncopal reactions.

Have a written protocol to manage medical emergencies following vaccination.

Health care personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

For COVID-19 vaccines given under an Emergency Use Authorization (EUA), vaccination providers are required to report to VAERS:

- Vaccine administration errors, whether or not associated with an adverse event.
- Serious adverse events regardless of causality. Serious adverse events per FDA are defined as:
  - Death
  - A life-threatening adverse event
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
  - A congenital anomaly/birth defect
  - 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.
  - Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
  - Cases of myocarditis
  - Cases of pericarditis
  - Cases of COVID-19 that result in hospitalization or death.

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to is available at Vaccine Adverse Event Reporting System (VAERS) or by calling 1-800-822-7967.

For More Information, Please See:

- Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination
- CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions"
- Medical Management of Vaccine Reactions in Children and Teens in a Community Setting
- Medical Management of Vaccine Reactions in Adults in a Community Setting

Note: For more information/guidance on the use of standing orders, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____effective_____ until rescinded or until _____ .

Medical director (or other authorized practitioner)

_____ / _____ /_____.

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders