12 Years of Age and Older

# Updated (2023–24 Formula) Novavax COVID-19 Vaccine

Standing Orders for Administering Vaccine



2023–24 Formula Vaccine Presentation	Age	Dose/Injection Amount	Route
Multidose vial with blue cap and blue label	12 years and older	0.5 mL/5 <i>μg</i> rS and 50 μg of Matrix-M™ adjuvant	Intramuscular (IM) injection
<b>Purpose</b> To reduce morbidity and mortality from coronavirus	<b>Policy</b> Where au	thorized under state law, stand	ling orders enable

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). 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 2023–24 Novavax COVID-19 Vaccine based on the following criteria:

#### People who are NOT moderately or severely immunocompromised<sup>\*</sup>

COVID-19 vaccination history <sup>†</sup> (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Novavax COVID-19 Vaccine
Unvaccinated	<ul> <li>Give a 2-dose initial series</li> <li>Dose 1 now.</li> <li>Dose 2 at least 3-8 weeks<sup>‡</sup> after Dose 1<sup>§</sup></li> </ul>
1 previous dose of the original Novavax COVID-19 Vaccine (Dose 1)	Give Dose 2 at least 8 weeks (2 months) after the previous dose
1 previous dose of 2023-24 Novavax COVID-19 Vaccine (Dose1)	Give Dose 2 at least 3-8 <sup><math>\ddagger</math></sup> weeks after the previous dose <sup>§</sup>
Any number of previous doses COVID-19 vaccine, NOT including at least 1 dose of 2023- 24 COVID-19 vaccine	Give 1 dose at least 8 weeks (2 months) after the previous dose
Any number of previous doses COVID-19 vaccine, INCLUDING at least 1 dose of 2023-24 COVID-19 vaccine	<b>People 12 through 64 years of age:</b> No further doses are indicated. <b>People 65 years of age and older:</b> Administer 1 additional dose at least 4 months following the previous dose of 2023-24 COVID-19 vaccine.

<sup>\*</sup> Persons with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).

+ COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent (ancestral) mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination

of the three, unless otherwise specified; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine

doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

<sup>+</sup> An 8-week interval between the first and second COVID-19 vaccine (Novavax) doses might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

<sup>§</sup> People who are recommended to receive a multidose series for initial vaccination should receive all doses from the same manufacturer. However, in the following circumstances a different age-appropriate COVID-19 vaccine product may be administered when: the same vaccine is not available at the vaccination site at the time of the clinic visit, the previous dose is unknown, the person would otherwise not receive a recommended vaccine dose, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication.

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#### People who ARE moderately or severely immunocompromised

COVID-19 vaccination history <sup>*</sup> (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Novavax COVID-19 Vaccine	
Unvaccinated	<ul> <li>Give a 2-dose initial series</li> <li>Dose 1 now.</li> <li>Dose 2 at least 3 weeks after Dose 1</li> </ul>	
1 previous dose of the original Novavax COVID-19 vaccine (Dose 1) <sup>†</sup>	Give Dose 2 at least 8 weeks (2 months) after the previous dose	
1 previous dose of 2023-24 Novavax COVID-19 Vaccine (Dose1) <sup>†</sup>	Give Dose 2 at least 3 weeks after the previous dose	
2 previous doses of Novavax COVID-19 vaccine, NOT including 2023-24 COVID-19 vaccine <sup>†</sup>	Give 1 dose at least 8 weeks (2 months) after the previous dose	
2 or more doses of Novavax COVID-19 vaccine, INCLUDING 2023-24 COVID-19 vaccine <sup>†</sup>	<ul> <li>People 5 through 64 years of age: May receive 1 additional dose at least 8 weeks (2 months) following the previous dose of 2023-24 COVID-19 vaccine.</li> <li>Further additional dose(s) may be administered, informed by the clinical judgement of a health care provider and personal preference and circumstances.</li> <li>Administer any further additional doses at least 8 weeks (2 months) after the last 2023-24 COVID-19 vaccine dose.</li> </ul>	
	<ul> <li>People 65 years of age and older: Administer 1 additional dose at least 8 weeks (2 months) following the previous dose of 2023-24 COVID-19 vaccine.</li> <li>Further additional dose(s) may be administered, informed by the clinical judgement of a health care provider and personal preference and circumstances.</li> <li>Administer any further additional doses at least 8 weeks (2 months) after the last 2023-24 COVID-19 vaccine dose.</li> </ul>	

\* COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent (ancestral) mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses.

+ People who are recommended to receive a multidose series for initial vaccination should receive all doses from the same manufacturer. However, in the following circumstances a different age-appropriate COVID-19 vaccine product may be administered when: the same vaccine is not available at the vaccination site at the time of the clinic visit, the previous dose is unknown, the person would otherwise not receive a recommended vaccine dose, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication.

## Additional clinical considerations

- 2023–24 Novavax COVID-19 Vaccine may be simultaneously administered with other routinely recommended vaccines. There are <u>additional</u> <u>considerations</u> for simultaneous administration of an orthopoxvirus vaccine and COVID-19 vaccine.
- Persons who have received HCT or CAR-T-cell therapy
- Revaccinate persons who received 1 or more 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 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- For additional details and all clinical considerations, see <u>Interim Clinical Considerations for Use of COVID-19</u> <u>Vaccines</u>.

## **Contraindications:**

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

<sup>‡</sup> See FDA fact sheet for a full list of vaccine ingredients.



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### **Precautions:**

- Moderate to severe acute illness, with or without fever
- History of:
  - A diagnosed non-severe allergy to a component of Novavax COVID-19 vaccine<sup>‡</sup>
  - Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of Novavax COVID-19 vaccine
  - 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 <u>Fact Sheet for Recipients and Caregivers</u>.
- Prepare to administer the vaccine following the manufacturer's guidance. Choose the correct <u>needle</u> <u>gauge</u>, <u>needle length</u>, <u>and injection site</u> for persons:
  - 12 through 18 years of age:
    - » Needle gauge/length: 22–25 gauge, 5/8<sup>\*</sup> -1-inch
    - » Site: Deltoid muscle of arm<sup>+</sup>
  - 19 years of age and older: See chart below.
- Administer Novavax COVID-19 Vaccine by intramuscular (IM) injection 0.5 mL/5 μg.

\* 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.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site $^{\dagger}$
Female or male less than 130 lbs	22–25	5/8 <sup>‡</sup> –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+ Ibs	22–25	1.5"	Deltoid muscle of arm
Male 260+ lbs	22–25	1.5"	Deltoid muscle of arm

+ 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.



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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)

Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:

- Vaccine administration errors, whether or not associated with an adverse event
- Serious adverse events, irrespective of attribution to vaccination
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- 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 VAERS is available at <u>Vaccine Adverse Event Reporting System (VAERS) (hhs.gov)</u> 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"
- <u>Medical Management of Vaccine Reactions in Children</u> and Teens in a Community Setting
- Medical Management of Vaccine Reactions in Adults in a Community Setting

**Note:** For more information/guidance, 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		
- <u></u> .				
Medical director (or other authorized practitioner)				
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Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders