

Novavax COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older



Vaccine Product	Dose/Injection Amount	Route
Blue capped vial	5 µg rS and 50 µg of Matrix-M™ adjuvant/0.5 mL	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 healthcare 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 18 years of age and older for vaccination with Novavax COVID-19 Vaccine based on the following criteria:

Persons who **are NOT** moderately or severely immunocompromised*†

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of Novavax COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
 - Novavax COVID-19 Vaccine, administer the second dose at least 3 to 8 weeks after the first dose.
 - A vaccine product that cannot be determined, is no longer available or contraindicated, administer Novavax COVID-19 Vaccine at least 4-8 weeks after the first dose.

Persons who **ARE** moderately or severely immunocompromised†

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of Novavax COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
 - Novavax COVID-19 Vaccine, administer the second dose at least 3 weeks after Dose 1.
 - A vaccine product that cannot be determined, is no longer available or contraindicated, administer Novavax COVID-19 Vaccine at least 4 weeks after the first dose.

- Persons with a history of myocarditis or pericarditis:
 - If history is prior to COVID-19 vaccination, may receive Novavax COVID-19 Vaccine, after the episode of myocarditis or pericarditis has completely resolved.
 - If myocarditis or pericarditis occurred after the first dose of an mRNA or Novavax COVID-19 vaccine, generally experts advise no additional doses of any COVID-19 vaccine. Administration of the second dose of an mRNA or Novavax COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis>
- Additional clinical considerations
 - For people who received a COVID-19 vaccine outside the United States, guidance can be found at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a>
 - Novavax COVID-19 Vaccine may be coadministered with other routinely recommended vaccines without regard to timing, including simultaneous administration.
 - For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection>
- Persons who have received HCT or CAR-T-cell therapy
 - Revaccinate persons who received doses of COVID-19 vaccine prior to or during receiving HCT or CAR-T-cell therapy with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- Screen for contraindications and precautions.
 - **Contraindications**
 - » History of a:
 - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
 - Known diagnosed allergy to a component of the vaccine (see <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C> for a list of vaccine components)

* Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

† Inform parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of an mRNA or Novavax COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. Educational materials are available at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>

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○ Precautions

- » Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- » History of:
 - Immediate allergic reaction to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])^{‡§}
 - Non-severe, immediate (onset less than 4 hours after vaccination), allergic reaction to a previous dose of the COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine[¶]
 - Allergy-related contraindication to one type of COVID-19 vaccine have precaution to other types of COVID-19 vaccines
 - Moderate to severe acute illness, with or without fever
 - History of MIS-C or MIS-A
 - History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site**
Female or male fewer 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	1–1½"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
 - 18 years of age:
 - » Needle gauge/length: 22-25 gauge, 1-inch
 - » Site: Deltoid muscle of arm.
 - 19 years of age and older: See chart on page 2.
 - Follow the manufacturer's guidance for storing/handling punctured vaccine vials.
 - Administer 0.5 mL Novavax COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
 - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
- 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 card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
 - » Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.novavaxcovidvaccine.com.
- Be prepared to manage medical emergencies.

‡ Vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist.
§ An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.
¶ People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types. Consider consultation with an allergist-immunologist to help determine if a patient with a contraindication to an Novavax can safely receive another COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.
** Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.
†† 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).

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- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
 - » **30 minutes:** Persons with a history of:
 - A contraindication to another type of COVID-19 vaccine product.
 - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
 - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
 - Anaphylaxis due to any cause.
 - History of a non-severe, immediate allergic reaction after a previous dose of COVID-19 vaccine
 - » **15 minutes:** All other persons
- Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare 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.
- For more information, please see:
 - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.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.html>**
- » **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at <https://www.immunize.org/catg.d/p3082.pdf>**
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
 - While this vaccine is under [Emergency Use Authorization \(EUA\)](#), healthcare professionals are required to report to VAERS:
 - » Vaccine administration errors (whether associated with an adverse event [AE] or not)
 - » Serious AEs (irrespective of attribution to vaccination)
 - » Multisystem inflammatory syndrome (MIS) in [adults](#) or [children](#)
 - » Cases of COVID-19 that result in hospitalization or death
 - » Any additional AEs and revised safety requirements per the [Food and Drug Administration's](#) conditions for use of an authorized vaccine throughout the duration of the EUA
 - Healthcare professionals are encouraged to report to [VAERS](#):
 - » Clinically important adverse events that occur after vaccination, even if they are not sure whether the vaccine caused the adverse event

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