# Standing Order for Administering Novavax/Nuvaxovid© COVID-19 Vaccine (Adolescents and Adults ≥ 12 years of age)

**Purpose:** To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all individuals ≥ 12 years of age who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) licensure or Emergency Use Authorization (EUA), and the Department of Defense (DOD).

**Policy:** Under these standing orders, eligible healthcare professionals working within their scope of practice may vaccinate patients who meet the criteria below.

**Procedure:**

1. Novavax/Nuvaxovid© COVID-19 vaccine is FDA-authorized under EUA for individuals ≥ 12 years of age as 2-dose primary series. See table 1 for dosing intervals.
2. Novavax/Nuvaxovid© COVID-19 vaccine is not authorized for use as either a homologous or heterologous booster dose.
3. Individuals vaccinated outside the United States who received all or some of:
   - An FDA-licensed or FDA-authorized COVID-19 vaccine, a World Health Organization emergency use listed (WHO-EUL) COVID-19 vaccine not FDA-licensed or FDA-authorized, or a heterologous (mix and match) series from those two groups: do not restart the series in the U.S. Receive subsequent doses according to Table 1.
   - A non WHO-EUL COVID-19 vaccine primary series: doses do not count towards U.S. vaccination. Start a primary series ≥ 28 days after the last dose and receive subsequent doses according to Table 1.
4. Novavax/Nuvaxovid© COVID-19 vaccine and other vaccines may be co-administered without regard to timing, including same-day administration, with one exception: per DoD policy, ACAM2000™ smallpox vaccine must be separated from any COVID-19 vaccine by ≥ 28 days. There is no minimum interval between vaccination with Novavax COVID-19 vaccines and vaccination with JYNNEOS® Monkeypox/Smallpox vaccine. People, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving a Novavax COVID-19 vaccine because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and mRNA and Novavax COVID-19 vaccines and the unknown risk for myocarditis and pericarditis after JYNNEOS.
5. Defer receipt of tixagevimab/cilgavimab (EVUSHELD™) for ≥ 2 weeks after vaccination with Novavax/Nuvaxovid© COVID-19 vaccine. There is no recommended deferral period for vaccination after receipt of passive antibody therapy (e.g., anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma).
6. Using DHA Form 207, screen all patients for contraindications and precautions to the COVID-19 vaccine:
   **Contraindications:**
   - A history of a serious allergic reaction (e.g., anaphylaxis) or diagnosed allergy to a previous dose or component of a Novavax/Nuvaxovid© COVID-19 vaccine, to include polysorbate (see the FDA fact sheet/package insert for a complete list of excipients).

   **Precautions:**
   - History of an immediate allergic reaction to any injectable medication.
   - An allergy-related contraindication to another type of COVID-19 vaccine (e.g., mRNA

[Moderna or Pfizer] or adenovirus vector [Janssen]).*

- Moderate or severe acute illness with or without fever.
- History of MIS-C or MIS-A.
- Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine.*
- Syncope (fainting) can occur in association with administration of injectable vaccines. Have procedures in place to avoid a falling injury (e.g., observation after administration) and to restore cerebral perfusion following syncope.
- For questions or concerns, consider consulting the DHA Immunization Healthcare Support Center at (877) 438-8222, Option 1 or DSN 761-4245.

***Note:***

****A subsequent dose or alternative COVID-19 vaccine may be considered using shared clinical decision-making but is not covered under these standing orders: these patients must obtain a written order from a privileged provider.***

7. **Special Populations:**
   - **Pregnancy:** Pregnant and postpartum individuals may receive any current FDA-licensed or FDA EUA-authorized COVID-19 vaccine, to include additional primary or booster doses. Data on the safety of COVID-19 vaccines in pregnancy is limited, but reassuring. Individuals vaccinated during pregnancy should be encouraged to enroll in the Novavax COVID-19 Pregnancy Registry by visiting https://c-viper.pregistry.com/. Routine pregnancy testing before receipt of COVID-19 vaccine is not indicated, and pregnancy need not be delayed after vaccination.
   - **Lactation:** COVID-19 vaccination is recommended for all lactating individuals. SARS-CoV-2 antibodies have been found in the breast milk of individuals who have received COVID-19 vaccines, suggesting a potential protective effect against infection in the infant. The degree of clinical benefit, if any, is not yet known.
   - **Immunocompromised:** Individuals who are moderately or severely immunocompromised may be at increased risk for severe COVID-19. Currently there is no recommendation for additional primary doses of Novavax/Nuvaxovid© COVID-19 vaccine for this group. These individuals should discuss COVID-19 vaccine receipt timing and medication management with their primary or specialty healthcare provider. Immunocompromising conditions can include (but are not limited to):
     - Generalized malignancy.
     - Solid organ or stem cell transplant.
     - Congenital or acquired immunodeficiencies (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome, HIV/AIDS, or lymphocyte or complement deficiencies).
     - Iatrogenic immunosuppression (e.g., treatment with immunosuppressive drugs, including long-term systemic corticosteroids, biologics, or radiation therapy).
8. Provide all patients (or their parent/legal representative) with a copy of the Novavax/Nuvaxovid© COVID-19 vaccine Information Fact Sheet for Recipients and Caregivers or the VIS, as applicable. Provide non-English speaking patients with a copy in their native language, if available and preferred.
9. Provide Novavax/Nuvaxovid© COVID-19 vaccine as follows:

**Table 1: Dosing Intervals**

| COVID-19 Vaccine Product | Number of primary doses | Interval: 1st and 2nd primary dose | Interval: primary series and (Moderna or Pfizer-BioNTech) bivalent booster dose* |
|---|---|---|---|

| Novavax/Nuvaxovid© | ≥ 12 years | | |
|---|---|---|---|
| • **Immunocompetent**<br>• **Immunocompromised** | 2 | 3-8 weeks† | ≥ 2 months |

*Bivalent booster recommended for all individuals ≥ 12 years of age, regardless of the number of previous monovalent booster doses received. (see respective Pfizer or Moderna Standing Orders for bivalent booster vaccine administration; Novavax is not authorized as a booster vaccine)

†An 8-week interval may be optimal for some individuals ≥ 12 years of age, especially for males 12-39 years of age. A shorter interval (3 weeks for Novavax) between the 1st and 2nd doses remains the recommended interval for immunocompromised individuals; adults ≥ 65 years of age; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

- Using a sterile needle and 1mL syringe, administer 0.5mL of Novavax/Nuvaxovid© COVID-19 vaccine intramuscularly according to Table 1. Separate multiple injection sites by 1 inch or more and if possible, administer COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs.

10. Dosing intervals:
    - While overall risk of myocarditis remains small, it is higher for males 12-39 years of age; this risk might be reduced by extending the interval between the 1st and 2nd primary dose to 8 weeks.
    - A 3-week interval between the 1st and 2nd primary doses is recommended for moderately to severely immunocompromised individuals; adults ≥ 65 years of age; and individuals needing rapid protection due to increased concern for community transmission or risk of severe disease.
    - DO NOT compress minimum intervals for clinic convenience. However, doses administered ≤ 4 days (the "grace period") before the minimum interval (e.g., prior to imminent travel, immunosuppressive therapies, etc.) are considered valid.
    - Any COVID-19 vaccine dose administered earlier than allowed by the grace period is invalid and should be repeated. Space the repeat dose after the dose given in error by at least the minimum interval.
    - COVID-19 vaccines are NOT interchangeable for initial vaccination: complete the **primary series** with the same product.

| **IM Needle Length and Injection Site Guidelines**<br>• Use a 22 – 25 gauge needle<br>• Choose needle gauge and length appropriate to the patient's age, sex, and body mass | | |
|---|---|---|
| **Age group** | **Needle length** | **Injection site** |
| **Adolescents and Adults (≥ 12 years)** | | |
| Men and women, <60 kg (130 lbs) | 5/8 -1 inch (16-25 mm)* | Deltoid muscle of arm† |
| Men and women, 60-70 kg (130-152 lbs) | 1 inch (25 mm) | |
| Men, 70-118 kg (152-260 lbs) | 1-1.5 inches (25-38 mm) | |
| Women, 70-90 kg (152-200 lbs) | | |
| Men, >118 kg (260 lbs) | 1.5 inches (38 mm) | |
| Women, >90 kg (200 lbs) | | |
| Men and women, any weight | 1.5 inches (38 mm)§ | Anterolateral thigh |

Adapted from the CDC General Best Practice Guidelines for Immunization - Vaccine Administration: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html

* Some experts recommend a 5/8-inch needle for men and women who weigh <60 kg if skin is stretched tightly and subcutaneous tissue is not bunched.

† Preferred site: the alternate site (anterolateral thigh) may be used if the muscle mass at the preferred site is inadequate. Do not administer vaccine into the gluteal muscle.

§Some experts recommend a 1-inch needle at this site if skin is stretched tightly and subcutaneous tissue is not bunched.

11. Storage and use of vials Novavax/Nuvaxovid© COVID-19 vaccine:
    - **DO NOT DILUTE BEFORE USE**.
    - Novavax/Nuvaxovid© COVID-19 vaccine is supplied in 5.5mL multiple-dose vials containing 10 doses of 0.5mL each.
    - Store unpunctured vials in a refrigerator at 2°C to 8°C (36°F to 46ºF).
    - **Do not freeze.**
    - Swirly vial gently before each withdrawal: **do not shake**.
    - Mark vials with the date and time of first use.
    - Do not pool excess vaccine from multiple vials.
    - Store punctured vials at 2°C to 25°C (36°F to 77°F) and discard 6 hours after first puncture.
12. Provide all individuals (or their parent/legal representative) with information on the v-safe program and strongly encourage them to enroll. V-safe is an app that provides personalized health check-ins and dose reminders after receipt of a COVID-19 vaccine.
13. Document all immunizations administered in the patient's electronic health record and the appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, and the identification of the individual administering the vaccine. If vaccine was not given, record the reason for non-receipt.
14. **Mandatory observation.** Observe all individuals who receive any COVID-19 vaccine post-administration according to the following guidelines:
    - **30 minutes** - individuals with:
        - Allergy-related contraindication to a different type of COVID-19 vaccine
        - Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
        - Anaphylaxis after non-COVID-19 vaccines or injectable therapies
    - **15 minutes**: all other individuals.
15. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.
16. It is **MANDATORY** for vaccination providers to file a report with the Vaccine Adverse Event Reporting System (VAERS) for all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome in adults (MIS-A) or children (MIS-C), and hospitalized or fatal cases of COVID-19 following vaccination with any COVID-19 Vaccine. Reports can be submitted to VAERS online at https://vaers.hhs.gov. Additional information about VAERS is also available by telephone (800-822-7967).
17. This policy and procedure shall remain in effect for all patients of the _____ until rescinded and/or upon a change in the Medical Director, whichever is earlier.

Medical Director’s Signature

Date