Standing Order for Administering Janssen COVID-19 Vaccine
(Recombinant adenovirus COVID-19 Vaccine Ad26.COV2.S)

Purpose: To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all persons 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) Emergency Use Authorization, and the Department of Defense (DoD).

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

Procedure:

1. For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

2. Screen all patients for contraindications and precautions to the COVID-19 vaccine.

3. COVID-19 and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 and other vaccines on the same day, as well as co-administration within 14 days.

4. Defer vaccination with Janssen COVID-19 vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.

Contraindications:

- A history of a serious reaction (e.g., anaphylaxis) after vaccination or to any vaccine component to include polysorbate (see the product fact sheet for complete list of excipients).*

Precautions:

- Moderate or severe acute illness with or without fever.
- Allergies: Persons with a history of severe allergic reaction (e.g. anaphylaxis) to an injectable medication should use caution when receiving the vaccine, and be observed by medical personnel for 30 minutes following administration.
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid a falling injury (e.g. 15-minute observation after administration) and to restore cerebral perfusion following syncope.
- COVID-19 Vaccine Clinical Trial Participants: anyone who reports they are in a clinical trial for a COVID-19 vaccine candidate needs to confer with their trial POCs before vaccination with Janssen COVID-19 vaccine.
- For questions or concerns, consider consulting the DHA Immunization Healthcare Division at (877) 438-8222, Option 1 or DSN 761-4245.

Note:

- ** Persons who have a contraindication to an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) may be able to receive the Janssen COVID-19 vaccine.*

- *Prior to administration of Janssen COVID-19 vaccine, inform women 18-49 years of age of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group. Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.*

Special Populations:

- **Pregnancy/Breastfeeding:** Pregnant, lactating, and post-partum persons are eligible for and can receive any currently authorized COVID-19 vaccine. Pregnant persons who contract COVID-19 have an increased risk of adverse pregnancy complications, severe illness, or death, though the absolute risk for these outcomes is low.

  Data on the safety of COVID-19 vaccines in pregnant persons are limited. Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or fetus. The current FDA-authorized COVID-19 vaccines cannot cause infection in either the mother or the fetus. Early data from vaccine-safety-related databases (VAERS and V-SAFE) did not identify any safety concerns for pregnant persons who were vaccinated or for their babies. Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant persons are underway or planned.

- **Immunocompromised:** Persons with immunocompromising conditions or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. No data are available to establish COVID-19 vaccine safety and efficacy or optimal dose timing in these groups. However, the currently authorized COVID-19 vaccines are not live vaccines, therefore can be safely administered to immunocompromised persons.

5. Provide all patients (or their parent/legal representative) with a copy of the Emergency Use Authorization (EUA) fact sheet for recipients and caregivers. Provide non-English speaking patients with a copy in their native language, if available and preferred.

6. Provide vaccine as follows:
   - The complete series of the Janssen COVID-19 vaccine consists of one dose.
   - Administer 0.5mL intramuscularly in the deltoid muscle.
   - Vials are initially stored frozen by the manufacturer, then shipped at 2°C to 8°C. If vaccine is still frozen upon receipt, thaw in a refrigerator at 2°C to 8°C: **do not store frozen.**
   - If needed immediately, thaw vials at room temperature (up to 25ºC) (one carton [10 vials] takes approximately 4 hours to thaw; one vial will take approximately 1 hour).
   - Unpunctured vials may be stored at 2°C to 8°C, protected from light, until ready to use.
   - Alternatively, unpunctured vials may be stored at 9°C to 25°C for up to 12 hours.
   - **Do not refreeze once thawed.**
   - Swirl vial gently for 10 seconds before/between each withdrawal. **Do not shake**; do not dilute.
   - After the first puncture, vials should be marked with the date and time.
   - Punctured vials may be stored at 2°C to 8°C for up to 6 hours or at room temperature (up to 25°C) for up to 2 hours, and then must be discarded.
   - Each vial contains five doses of 0.5mL.
   - Do not pool excess vaccine from multiple vials.

IM Needle Length and Injection Site for Adults		
Use a 22 – 25 gauge needle. Choose needle gauge and length appropriate to administration route and the patient's age and body mass.		
Patient sex and weight	**Needle Length**	**Injection Site**
Men and Women (<130 lbs)	1 inch†	
Men and Women (130-152 lbs)	1 inch	
Men (152-260 lbs)	1-1.5 inches	
Women (152-200 lbs)		
Men (> 260 lbs)	1.5 inches	
Women (>200 lbs)		

Adapted from 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 <130 lbs: stretch skin tightly (do not bunch subcutaneous tissue)

7. Provide all patients with the V-safe enrollment sheet and strongly encourage them to enroll in the program. V-Safe is a smart phone-based tool that uses text messaging and web surveys to provide personalized health check-ins after a patient receives a COVID-19 vaccination. It also reminds the patient of additional dose timing, when applicable.

8. COVID-19 vaccines are not interchangeable. If a person has received one previous dose of a different COVID-19 vaccine, the same brand should be used to complete the applicable series.

9. 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 person administering the vaccine. If vaccine was not given, record the reason for non-receipt. The CVX code for Janssen COVID-19 vaccine is 212.

10. **Mandatory observation.** All persons who receive any COVID-19 vaccine will be observed post-administration according to the following guidelines:
    - **30 minutes** - persons with:
        - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy.
        - Contraindication to Pfizer-BioNTech or Moderna COVID-19 vaccine who receive Janssen COVID-19 vaccine.
        - History of anaphylaxis due to any cause.
    - **15 minutes**: all other persons.

11. 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.

12. 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, by fax, or by mail. Additional information about VAERS is available by telephone (800-822-7967) or online at https://vaers.hhs.gov.

13. 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