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. Janssen COVID-19 Vaccine is authorized under EUA for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.
2. A single booster dose of Janssen COVID-19 vaccine given at least 2 months after completion of a primary dose of the Janssen COVID-19 vaccine is authorized under EUA for the prevention of COVID-19 caused by SARS-CoV-2 in certain individuals 18 years of age and older.
3. Janssen COVID-19 vaccine and other vaccines may be administered without regard to timing. This includes simultaneous administration with other vaccines on the same day, as well as co-administration within 14 days. Separate 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. The one exception to simultaneous vaccine administration is with ACAM2000™ smallpox vaccine. Per DoD policy, ACAM2000™ vaccine must be separated from any COVID-19 vaccine by at least 28 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.
5. Screen all patients for contraindications and precautions to the COVID-19 vaccine:

Contraindications:

- A history of a serious reaction (e.g., anaphylaxis) after vaccination or to any vaccine component to include polysorbate-80 (see the product fact sheet for complete list of excipients). PEG allergy is NOT a contraindication to Janssen COVID-19 vaccine but it is a precaution.

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.
- Myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine: until additional safety data are available, these persons should defer the second dose. †
- 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 Support Center at (877) 438-8222, Option 1 or DSN 761-4245.

Note:

- *† In certain circumstances a second dose or alternative COVID-19 vaccine may be considered, but should be based on shared clinical decision-making and is not covered under these standing orders. Patients must obtain a written order from a privileged provider for this situation.*

Special Populations:

- **Pregnancy/Breastfeeding**: Pregnant, lactating, and post-partum women are eligible for and can receive any currently approved or authorized COVID-19 vaccine. Pregnant women 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 women is limited. Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant woman or fetus. Janssen COVID-19 Vaccine 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 vaccinated pregnant women or for their babies. Clinical trials to evaluate the safety and efficacy of Janssen COVID-19 Vaccine in pregnant women are underway or planned. There is an exposure registry that monitors outcomes in women exposed to Janssen COVID-19 Vaccine during pregnancy. Women who are vaccinated with Janssen COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com.

- **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 approved and authorized COVID-19 vaccines are not live vaccines, therefore can be safely administered to immunocompromised persons. A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after primary vaccination with the Janssen COVID-19 Vaccine, to individuals 18 years of age and older. Immunocompromised patients should discuss COVID-19 vaccine receipt timing and medication management with their primary or specialty healthcare provider.

- **Booster doses:** A single booster dose of Janssen COVID-19 Vaccine at least 2 months after the primary series is authorized under EUA for certain individuals:
  - People 65 years and older
  - People 18 years and older who live in long-term care settings
  - People18 years and older with underlying medical conditions
  - People18 years and older who work or live in high-risk settings

  A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered as a heterologous (mix and match) booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous (mix and match) booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

6. Provide all patients (or their parent/legal representative) with a copy of the Janssen COVID-19 Vaccine 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.

7. Provide Janssen COVID-19 vaccine as follows:
    - A 1-dose primary series (0.5mL each).
    - A single booster dose (0.5 mL) at least 2 months after completing the primary series of any approved or authorized COVID-19 vaccine to certain individuals:
        - 65 years of age and older, as well as residents in long-term care settings.
        - 18-64 years of age at high risk of severe COVID-19 due to underlying medical conditions.
        - 18-64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19.
    - Using a sterile needle and 1mL syringe, administer 0.5mL intramuscularly in the deltoid muscle.
    - The Janssen COVID-19 vaccine is supplied in multiple-dose vials:
        - Each vial contains 5 doses of 0.5mL.
    - The vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F).
    - **Do not store frozen.**
    - Store unpunctured vials at 2°C to 8°C (36°F to 46°F) and protect from light.
    - Unpunctured vials may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.
    - If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature, a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw.
    - **Do not refreeze once thawed.**
    - Record the date and time of first puncture/use on the vial label**.**
    - After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours.
    - Discard the vial if vaccine is not used within these times.
    - Do not pool excess vaccine from multiple vials.

<table>
<tr><th colspan="3">IM Needle Length and Injection Site for Adolescents & Adults</th></tr>
<tr><td colspan="3">Use a 22 – 25 gauge needle. Choose needle gauge and length appropriate to administration route and the patient's age and body mass.</td></tr>
<tr><th>Patient sex and weight</th><th>Needle Length</th><th>Injection Site</th></tr>
<tr><td>All patients 12 – 18 years of age</td><td>1 inch</td><td rowspan="8">Deltoid Muscle of Arm</td></tr>
<tr><td>Men and Women (<130 lbs)</td><td>1 inch†</td></tr>
<tr><td>Men and Women (130-152 lbs)</td><td>1 inch</td></tr>
<tr><td>Men (152-260 lbs)</td><td>1-1.5 inches</td></tr>
<tr><td>Women (152-200 lbs)</td><td rowspan="2">1-1.5 inches
1.5 inches</td></tr>
<tr><td>Men (> 260 lbs)</td></tr>
<tr><td>Women (>200 lbs)</td><td>1.5 inches</td></tr>
</table>

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)

8. 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.
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 207.

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/COMIRNATY® 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