

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:

Contraindications:

- A history of a serious reaction (e.g., anaphylaxis) to any vaccine component to include polysorbate 80. (see 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.
- Persons with a contraindication to mRNA COVID-19 Vaccines have a precaution to the Janssen COVID-19 vaccine. Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive the vaccination.
- 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.
- For questions or concerns, consider consulting the DHA Immunization Healthcare Division at (877) 438-8222, Option 1 or DSN 761-4245.

Special Populations:

- **Pregnancy:** There is limited data on the use of Janssen COVID-19 vaccine in pregnant women. Animal reproductive toxicity studies showed no vaccine-related adverse effects on fertility or embryo/fetal/postnatal development. Pregnant women desiring the Janssen COVID-19 vaccine may discuss the risks and benefits of such vaccination with their obstetrics provider. ACIP recommendations currently state any of the currently authorized COVID-19 vaccines can be administered to pregnant people.
 - **Breastfeeding:** It is unknown whether Janssen COVID-19 vaccine is excreted in human milk; therefore, risk to newborns or infants cannot be excluded. ACIP recommendations state any of the currently authorized COVID-19 vaccines can be administered to lactating people.
 - **Immunocompromised:** People with HIV infection or other immunocompromising conditions or people 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 in these groups. However, the currently authorized COVID-19 vaccines, to include the Janssen COVID-19 vaccine are not live vaccines and therefore can be safely administered to immunocompromised people.
3. 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.

4. Provide vaccine as follows:
 - A complete series of the Janssen COVID-19 vaccine consists of a single dose.
 - Administer 0.5mL intramuscularly in the deltoid muscle.
 - Unpunctured multidose vials may be stored at 2°C to 8°C for up to 3 months; protect from light; do not store frozen.
 - Unpunctured multidose vials may be stored at 9°C to 25°C for up to 12 hours.
 - After the first puncture, vials may be stored at 2°C to 8°C for up to 6 hours or at room temperature (25°C max) for up to 2 hours, and then must be discarded.

Needle Length and Injection Site of IM Injections 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.		
Age Group	Needle Length	Injection Site
Men and Women (<130 lbs)	1 inch†	Deltoid Muscle of Arm
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; skin must be stretched tightly (do not bunch subcutaneous tissue).

5. 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.
6. 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.
7. 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.
8. 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 (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Janssen COVID-19 Vaccine. Reports can be submitted to VAERS online. Additional information about VAERS is available by telephone (800-822-7967) or online at <https://vaers.hhs.gov>.
9. These policies and procedures 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