Standing Order for Administering Pfizer-BioNTech COVID-19 Vaccine
(COVID-19 mRNA Vaccine BNT162b2)

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 12 years of age and older.

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

3. Defer vaccination with Pfizer-BioNTech 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 polyethylene glycol (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 Pfizer-BioNTech 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.

4. 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.

5. Provide vaccine as follows:
   - The Pfizer-BioNTech COVID-19 vaccine is a 2-dose series spaced at least 21 days apart (no maximum limit but preferably before 42 days).
   - Using a sterile needle and 1mL syringe, administer 0.3mL of appropriately diluted vaccine intramuscularly in the deltoid muscle.
   - Vials must be kept frozen and protected from light, in the original cartons, until ready to use.
   - Undiluted vials should be stored in an ultra-low freezer at -80°C to -60°C until the expiration date on the vial.
   - Alternatively, undiluted vials may be stored at -25°C to -15°C for up to 2 weeks. Total cumulative time vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks. These vials may be returned to ultra-low storage (-80°C to -60°C) **one time**.
   - Undiluted vials may be thawed and stored refrigerated (2°C to 8°C) for up to 5 days (120 hours). Cartons may take two to three hours to thaw.
   - For immediate use, thaw undiluted vials at room temperature (up to 25°C) for 30 minutes. Thawed vials can be exposed to room light.
   - Vials must reach room temperature before dilution.
   - Undiluted vials may be stored at room temperature for no more than 2 hours.
   - Dilute multidose vials as follows (also see graphic on page 5):
     - Allow thawed vial to sit at room temperature (up to 25°C) for 30 minutes.
     - Gently invert vaccine vial 10 times prior to dilution; **do not shake**.
     - Withdraw 1.8mL of diluent (use sterile non-bacteriostatic 0.9% sodium chloride injection USP only) using a 21 gauge or narrower needle and aseptic technique.
       - Add diluent to the vaccine vial; equalize vial pressure before removing the needle by withdrawing 1.8 mL of air into the empty diluent syringe.
       - Gently invert the vaccine vial 10 times; **do not shake**.
Vials of diluted vaccine should be marked with the dilution date and time.

- Diluted vaccine should be stored at 2°C to 25°C and used within 6 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and UV light.
- Once thawed, do not refreeze.
- After dilution, one vial contains up to six doses of 0.3 mL: do not pool excess vaccine from multiple vials.
- Vial labels and cartons may state that after dilution, a vial contains five doses of 0.3 mL. The information in this Standing Order regarding the number of doses per vial after dilution is per the most current FDA EUA and supersedes the number of doses stated on vial labels and cartons.

**IM Needle Length and Injection Site for Adolescents & Adults**

Use a 22 – 25 gauge needle. Choose needle gauge and length appropriate to administration route and the patient’s age and body mass.

<table>
<thead>
<tr>
<th>Patient sex and weight</th>
<th>Needle Length</th>
<th>Injection Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients 12 – 16 years of age</td>
<td>1 inch</td>
<td>Deltoid Muscle of Arm</td>
</tr>
<tr>
<td>Men and Women (&lt;130 lbs)</td>
<td>1 inch†</td>
<td></td>
</tr>
<tr>
<td>Men and Women (130-152 lbs)</td>
<td>1 inch</td>
<td></td>
</tr>
<tr>
<td>Men (152-260 lbs)</td>
<td>1-1.5 inches</td>
<td></td>
</tr>
<tr>
<td>Women (152-200 lbs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men (&gt; 260 lbs)</td>
<td>1.5 inches</td>
<td></td>
</tr>
<tr>
<td>Women (&gt;200 lbs)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration

[http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html](http://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)

6. 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.

7. Observe a minimum interval of 21 days between the 1st and 2nd dose of the Pfizer-BioNTech COVID-19 vaccine. DO NOT compress the minimum interval between doses. Do not restart the primary series for any reason; resume the series with administration of the next dose. COVID-19 vaccines are NOT interchangeable: complete the series with the same product.

8. 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 Pfizer-BioNTech COVID-19 vaccine is 208.

9. **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 Janssen COVID-19 vaccine who receive Pfizer-BioNTech or Moderna COVID-19 vaccine.
     - History of anaphylaxis due to any cause.
   - **15 minutes**: all other persons.

10. 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.

11. 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](https://vaers.hhs.gov).

12. 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