Standing Order for Administering Pfizer-BioNTech/COMIRNATY® COVID-19 Vaccine (Adolescent & Adult ≥ 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. Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine is:
   - FDA-licensed as a 2-dose primary series for individuals ≥ 12 years of age.
   - FDA-authorized under EUA as a third primary series dose for individuals ≥ 12 years of age who are moderately or severely immunocompromised.
2. Pfizer-BioNTech Bivalent COVID-19 vaccine is FDA-authorized under EUA as a single booster dose for individuals ≥ 12 years of age. See Table 1 for all dosing intervals.
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. Pfizer-BioNTech/COMIRNATY® 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 mRNA COVID-19 vaccine by ≥ 28 days. There is no minimum interval between vaccination with Pfizer-BioNTech 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 Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and mRNA (i.e., Moderna and Pfizer-BioNTech) 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 Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine. There is no recommended vaccination deferral period after receipt of passive antibody therapy (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma).

***Notes**:*

- ***The FDA-licensed COMIRNATY® COVID-19 vaccine and the FDA EUA-authorized Pfizer-BioNTech COVID-19 vaccine have the same formulation and can be used interchangeably.***

- ***The Pfizer-BioNTech Bivalent COVID-19 vaccine can be used for booster doses only.***
- ***The Pfizer-BioNTech COVID-19 vaccines for individuals ≥ 12 years of age are distinctly different preparations than the Pfizer-BioNTech COVID-19 vaccines for other age groups. Ensure you are utilizing the correct standing order and product for your patient.***
- ***Individuals who will turn from 11 years to 12 years of age between their 1st and 2nd primary dose should receive the formulation appropriate for their age at the time of receipt.***

6. Using DHA Form 207, screen all individuals for contraindications and precautions to 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 Pfizer-BioNTech COVID-19 vaccine (see the FDA fact sheets for Pfizer-BioNTech/COMIRNATY® , Pfizer-BioNTech, and Pfizer-BioNTech Bivalent for a complete list of excipients).

Precautions:

- History of an immediate allergic reaction to any injectable medication or vaccine, or to polysorbate.
- An allergy-related contraindication to another type of COVID-19 vaccine (e.g., protein subunit [Novavax] or adenovirus vector [Janssen]).*
- History of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine is a precaution to the same type of COVID-19 vaccine.
- 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.***

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. Encourage individuals vaccinated during pregnancy to enroll in the Pfizer-BioNTech/ COMIRNATY® COVID-19 Pregnancy Registry (see registry information in Section 8.1 on page 18 of the package insert) and the CDC v-safe surveillance system. Routine pregnancy testing before receipt of COVID-19 vaccine is not required, 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 mRNA 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. These individuals should discuss COVID-19 vaccine receipt timing and medication management with their primary or specialty healthcare provider. These 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)
- **COVID-19 Vaccine Clinical Trial Participants**: Unless they have received or plan to receive additional doses through a clinical trial, participants (including moderately or severely immunocompromised people) who completed a primary series of a WHO-EUL COVID-19 vaccine (not a placebo) can receive additional age-appropriate mRNA COVID-19 vaccine doses as indicated. These individuals should confer with their trial POCs before vaccination.

7. Provide all patients (or their parent/legal representative) with a copy of the applicable Pfizer-BioNTech 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.
8. Provide Pfizer-BioNTech COVID-19 vaccine as follows:

Table 1: Dosing intervals

COVID-19 Vaccine Product	Number of primary doses	Interval: 1st and 2nd primary dose	Interval: 2nd and 3rd primary dose	Interval: primary series or last monovalent booster and bivalent booster dose*
Pfizer-BioNTech/COMIRNATY®	**≥ 12 years**			
• **Immunocompetent**	2	3-8 weeks†	NA	≥ 2 months
• **Immunocompromised**	3	3 weeks	≥ 4 weeks	≥ 2 months

*Bivalent booster recommended for all individuals ≥ 12 years of age, regardless of the number of previous monovalent booster doses received.

†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 Pfizer-BioNTech) 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 1 mL syringe, administer 0.3 mL of the appropriate vaccine intramuscularly in the deltoid muscle according to Table 2. Separate multiple injection sites by 1 inch or more and if possible, administer COVID-19 vaccines and vaccines that may be likely to cause a local reaction in different limbs.

9. 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.

Table 2: IM Needle Length and Injection Site for Adolescents & Adults

- Use a 22 – 25 gauge needle
- Choose needle gauge and length appropriate to the patient's age, sex, and body mass

Patient sex and weight	Needle Length	Injection Site
All individuals 12 – 16 years of age	1 inch	Deltoid Muscle of Arm
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: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html

† Some experts recommend a 5/8 inch needle for individuals who weigh <130 lbs: stretch skin tightly (do not bunch subcutaneous tissue)

10. Storage and use (see graphic on last page):

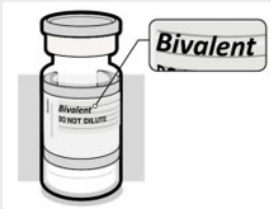
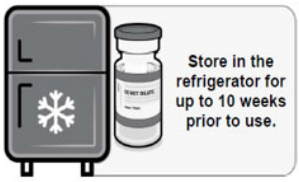
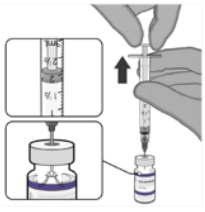
- Vials with a **purple cap and a label with a purple border:**
  - **DILUTE BEFORE USE** with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP.
  - After dilution, one multiple dose vial contains 6 doses of 0.3 mL.
  - Frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) until the expiry date. Some vials may remain in use beyond the expiry date if approved storage conditions have been maintained: information can be found here.
  - Frozen vials may also be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. These vials may be returned to ultra-low storage (-90°C to -60°C) **one time**.
  - Undiluted vials may also be thawed and stored in a refrigerator (2ºC to 8ºC [35ºF to 46ºF]) for up to 1 month.
  - Once thawed, **do not refreeze**.
  - Vials must reach room temperature before use.
  - Mark vials with the date and time of first puncture.
  - Do not pool excess vaccine from multiple vials.
  - Discard vials 6 hours after first puncture.
- Vials with a **gray cap and a label with a gray border** (primary series and bivalent booster):
  - **DO NOT DILUTE BEFORE USE.**
  - Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine is supplied in multiple dose vials containing 6 doses of 0.3 mL.
  - Pfizer Bivalent COVID-19 vaccine (**gray cap and a label with a gray border)** is supplied in two volumes:
    - Single dose vials containing 1 dose of 0.3 mL.
    - Multiple dose vials containing 6 doses of 0.3 mL.

- Frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC for up to 12 months: **do not store vials at -25°C to -15°C.**
- Vials may also be thawed and stored in a refrigerator at 2°C to 8°C (35ºF to 46ºF) for up to 10 weeks.
- Once thawed, **do not refreeze**.
- Vials must reach room temperature before use.
- Mark vials with the date and time of first puncture.
- Do not pool excess vaccine from multiple vials.
- Discard multiple dose vials 12 hours after the first puncture.
- Regardless of storage condition, vials should not be used after 12 months from the date of manufacture printed on the vial and cartons.

11. 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.
12. Document all immunizations administered in the patient's electronic health record and appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, VIS date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.
13. **Mandatory observation:** All individuals who receive any COVID-19 vaccine must be monitored as follows:
    - **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.
14. 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.
15. It is **MANDATORY** for vaccination providers to file a report with the Vaccine Adverse Event Reporting System (VAERS) for all vaccine administration errors, 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).
16. 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

	Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine: Purple cap	Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine: Gray cap (primary series and bivalent booster)
Verification	 ✓ Purple plastic cap and purple label border.	 ✓ Gray plastic cap and label with gray border. 
Thawing prior to use	• Thaw vial(s) in the refrigerator (2ºC to 8ºC [35ºF to 46ºF]) • A carton of vials may take up to 3 hours to thaw • Thawed vials can be stored in the refrigerator for up to 1 month • Allow vial(s) to sit at room temperature (up to 25ºC [77ºF]) for 30 minutes • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours 	• Thaw vial(s) in the refrigerator (2ºC to 8ºC [35ºF to 46ºF]) • A carton of 10 single dose vials may take up to 2 hours to thaw • A carton of 10 multiple dose vials may take up to 6 hours to thaw • Thawed vials can be stored in the refrigerator for up to 10 weeks • Allow vial(s) to sit at room temperature (up to 25ºC [77ºF]) for 30 minutes • Vials may be stored at room temperature for up to 12 hours prior to use 
Preparation 	• Before dilution invert vaccine vial gently 10 times • Do not shake • Prior to dilution the liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles • Do not use if liquid is discolored or if other particles are observed	• Before use, mix by inverting vaccine vial gently 10 times • Do not shake • Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles • After mixing, the vaccine should appear as a white to off-white suspension with no visible particles • Do not use if liquid is discolored or if particles are observed after mixing
Dilution 	• Diluent: use **ONLY** sterile 0.9% Sodium Chloride Injection, USP • Withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle) • Cleanse the vaccine vial stopper with an alcohol swab • Add 1.8 mL of diluent to the vaccine vial • Equalize vial pressure before removing the needle by withdrawing 1.8 mL air into the empty diluent syringe • Gently invert the vial 10 times to mix: do not shake • The vaccine will be an off-white suspension: do not use if vaccine is discolored or contains particulate matter	**Do not dilute**
Storage	 • Record the date and time of dilution on the vial label • Store between 2°C to 25°C (35°F to 77°F) • Discard any unused vaccine **6 hours** after dilution	 • Record the date and time of first vial puncture on the vial label • Store between 2°C to 25°C (35°F to 77°F) • Discard any unused vaccine **12 hours** after first puncture