

## Standing Order for Administering Pfizer-BioNTech COVID-19 Vaccine (Pediatric 5 -11 years of age)

**Purpose:** To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all children ages 5 -11 years 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 (EUA) and/or FDA-approval, 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. Pfizer-BioNTech COVID-19 vaccine is allowed under EUA for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 5 through 11 years of age.
2. A third primary series dose of Pfizer-BioNTech COVID-19 vaccine given at least 28 days after the second dose is allowed under EUA for individuals 5-11 years of age and up who are [moderately or severely immunocompromised](#).
3. Pfizer-BioNTech COVID-19 vaccine and other vaccines may be co-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 the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs.
4. 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.

### **Notes:**

- *The FDA-authorized Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years is a distinctly different preparation than the Pfizer-BioNTech/COMIRNATY® COVID-19 vaccines for adults (ages 12 years and older). Only the Pfizer-BioNTech preparation supplied in a multiple dose vial with an **orange cap** and a **label with an orange border** is authorized for use in individuals 5 through 11 years of age. Pfizer-BioNTech COVID-19 Vaccine that is supplied in vials with purple or gray caps should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors. **Ensure you are utilizing the correct standing order for your product.***
  - *Vial labels state "Age 5y to <12y". However, per FDA authorization, individuals who will turn from 11 years to 12 years of age **between** their first and second dose in the primary series may receive, **for either dose**, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age (0.2 mL dose from the vial with an orange cap); or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older (0.3 mL dose from the vial with a gray or purple cap).*
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 polyethylene glycol (see the [package insert](#) for a 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 any 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 dose of an mRNA COVID-19 vaccine: until additional safety data are available, these persons should defer additional doses.\*
- 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 Support Center at (877) 438-8222, Option 1 or DSN 761-4245.

### Note:

*\* In certain circumstances additional doses of Pfizer-BioNTech 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:

- **Immunocompromised:** An additional (3<sup>rd</sup>) dose for children 5-11 years of age who are moderately or severely immunocompromised is authorized by the FDA, is recommended by the CDC, and is authorized under this standing order. This dose should be given at least 28 days after completion of the 2-dose primary series.
- **Booster doses:** At this time, booster doses for children 5-11 years of age have not been authorized by the FDA nor recommended by the CDC and are NOT authorized under this standing order.

6. Provide all patients (or their parent/legal representative) with a copy of the [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.
7. Provide Pfizer-BioNTech COVID-19 vaccine supplied in multiple dose vials with **orange caps and labels with orange borders** as follows:
  - A 2-dose primary series (0.2mL each) spaced at least 21 days apart (no maximum limit but preferably before 42 days).
  - Using a sterile needle and 1mL syringe, administer 0.2mL of appropriately diluted vaccine intramuscularly in the deltoid muscle.
  - The Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years is supplied in multiple dose vials with **orange caps and labels with orange borders**:
    - After dilution, one vial contains 10 doses of 0.2mL.

- Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the [Full EUA Prescribing Information](#) supersedes the number of hours printed on vial labels and cartons.
- Frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F): **do not store vials at -25°C to -15°C (-13°F to 5°F)**.
- Undiluted vials may be stored at 2°C to 8°C for up to 10 weeks. Cartons may take up to four hours to thaw.
- If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature (8°C to 25°C [46°F to 77°F]) for 30 minutes.
- Vials may be stored at room temperature for a total of 12 hours prior to dilution.
- **Vials must reach room temperature before dilution.**
- Dilute multi-dose vials as follows (see graphic on pages 5-7):
  - 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 **1.3mL 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 1.3 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 (35°F to 77°F) and discarded after 12 hours.
- Once thawed, **do not refreeze**.
- Do not pool excess vaccine from multiple vials.
- Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

**Note:**

*The dilution of the Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years that is supplied in multiple dose vials with **orange caps and labels with orange borders** is a different dilution volume than what is used to dilute the Pfizer-BioNTech/COMIRNATY COVID-19 vaccine used in adults (persons 12 years and older). Be sure dilution for this Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years that is supplied in multiple dose vials with **orange caps and labels with orange borders** is only diluted with 1.3mL.*

IM Needle Length and Injection Site for Children		
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
All patients 5 – 11 years of age	1 inch	Deltoid Muscle of Arm

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration  
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>

8. Provide all patients (or their parent/legal representative) 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 provides reminders of additional dose timing, when applicable.

9. Observe a minimum interval of 21 days between the first and second dose of 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. Moderately or severely immunocompromised people ages 5-11 years should receive an additional primary dose of Pfizer- BioNTech COVID-19 vaccine administered  $\geq 28$  days after completion of the initial 2-dose series. COVID-19 vaccines from different manufacturers are NOT interchangeable: complete the series with the same product.
10. 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 in 5-11 year olds is 218.
11. **Mandatory observation.** Observe all persons who receive any COVID-19 vaccine 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.
    - History of anaphylaxis due to any cause.
  - **15 minutes:** all other persons.
12. 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.
13. 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>.
14. 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

**Dilution and Preparation Instructions**

**Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and a Label with Orange Border – VIAL VERIFICATION**



✓ Orange plastic cap and label with orange border.

- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states "Age 5y to < 12y."

**Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – THAWING PRIOR TO DILUTION**



- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
  - Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.

**Dilution and Preparation Instructions**

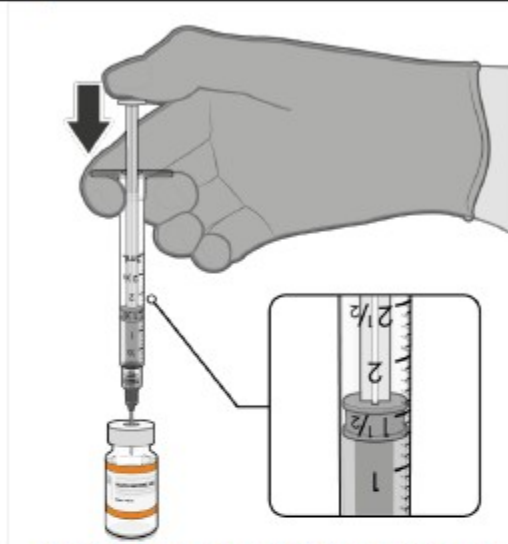


Gently × 10

- Before dilution, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

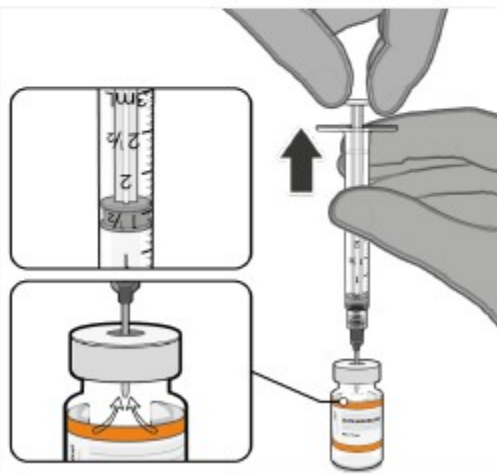
## Dilution and Preparation Instructions

### Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border - DILUTION



**Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.**

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.



**Pull back plunger to 1.3 mL to remove air from vial.**

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.

## Dilution and Preparation Instructions



**Gently × 10**

- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.



**Use within 12 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 dilution.